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ABSTRACT

New York State education law, rules, and regulations concerning the practice of pharmacy are presented. Provisions relating to the manufacture, sale, distribution, purity, potency, and labeling of drugs are included. State statutory provisions cover: licensing, duration and registration of a license, practice and regulation of the profession, supervision by the Board of Regents, administration by the Education Department, definitions of professional misconduct, proceedings in cases of professional misconduct, penalties for professional misconduct, and unauthorized acts. Additional concerns that are covered by the law include: registering and operating establishments; identification of pharmacists; seizure; shipment records; adulterating, misbranding and substituting; wrongful labeling; new drugs; certification of coal-tar colors for drugs and cosmetics; examinations and investigations; and factory inspection. Rules of the Board of Regents cover disciplinary proceedings, determination of good moral character in the professions, and unprofessional conduct. The regulations of the Commissioner of Education cover concerns such as educational requirements, experience, licensing examinations, and limited permits. Appendices include a list of New York State colleges of pharmacy. (SW)

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PHARMACY HANDBOOK

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The Pharmacy Handbook includes express terms of the Education Law and of the Rules and Regulations which have been adopted thereunder which apply to the practice of pharmacy. It includes also provisions relating to the manufacture, sale, distribution, purity, potency and labeling of drugs.

The Handbook is one of the reference materials required to be maintained in pharmacies by the Regulations of the Commissioner of Education. It is provided in loose-leaf form for ease and economy in revision. From time to time, replacement pages will be provided as changes in law, rule or regulation take place. The Handbook should be placed in a binder immediately upon receipt for ready reference and safekeeping.

PHARMACY HANDBOOK

The University of The State of New York
The State Education Department
State Board of Pharmacy
Cultural Education Center
Albany, New York 12230

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INTRODUCTION

Persons engaged in or planning to engage in the practice of pharmacy or in one of its related activities, such as the manufacture and distribution of drugs, are subject to the requirements of a vast body of law and regulation, both Federal and State. This Handbook is intended to provide the express terms of relevant sections of the Education Law, the Rules of the Board of Regents and the Regulations of the Commissioner of Education for the guidance of such persons in carrying out their activities in a lawful manner. Other laws which govern the several regulated activities are listed in the appendix.

The requirements are necessary in order to insure that the public is well served professionally by pharmacists and that the drugs distributed, sold and dispensed within the State meet standards for purity and potency and are properly labeled.

The Handbook will be of interest also to persons preparing for licensure in pharmacy, law enforcement officers, consumers and others.

PROFESSIONAL REGULATION IN NEW YORK STATE

In New York, regulation in 31 fields covered by Title VIII of the Education Law, comprising virtually all of the areas of practice traditionally called professions except teaching (which is subject to a separate body of law and regulation), law and theology, is vested in the Board of Regents of The University of the State of New York. State regulation includes the issuance of licenses and the enforcement of rules of professional conduct.

The New York system of professional regulation is unique in that it places a citizen body, the Board of Regents, responsible for education at all levels, in charge of the education, licensing and discipline of the professions. It is also unique in providing for boards to advise the Commissioner and the Regents on policy and on all matters relating to licensure and discipline. The boards, each aided by an Executive Secretary whom the Regents appoint, provide communication links to the professions and the public.

Bringing education, licensure and discipline together provides a wide scope of authority, accountability, and consistency

of policy across the professions. Centralizing data processing, examination and other licensing services, and the investigation and processing of professional discipline cases is also cost effective.

Under policy established by the Board of Regents, the Title VIII professions are administered through the following units of the Office of the Professions in the Office of Higher and Professional Education.

Professional Education and Professional Boards

The Department monitors programs of professional education according to standards for registration (accreditation) established by the Board of Regents. Specifically, through Board Executive Secretaries and consultants, the Department evaluates proposed new programs as well as currently registered programs in some 300 institutions that prepare individuals for the practice of one or more professions. Information concerning registered programs, including licensure-qualifying programs in the professions, may be obtained by contacting the appropriate Board office.

Twenty state boards for the professions are appointed by the Board of Regents to advise the Department and the Regents on matters relating to professional licensure, practice and conduct. The law provides that these boards comprise a number of licensed professionals and one or more "public members," consumers of the services provided by the profession concerned. Some 300 persons, including public members, serve on the twenty boards.

Questions regarding the practice of pharmacy may be directed to:

State Board of Pharmacy
New York State Education Department
Cultural Education Center
Room 3035
Albany, N.Y. 12230
Telephone - (Area Code 518) 474-3848, 7740, 7741

Professional Licensing Services

The Division of Professional Licensing Services (DPLS) of the State Education Department issues more than 50 different authorizations to practice in the 31 professions licensed or otherwise credentialed by the Department and Board of Regents. In cooperation with the Executive Secretary of the State Board in each licensed profession, the Division of Professional Licensing Services is responsible for enforcing licensing rules and regulations and assuring that the standards set by law are met prior to licensure.

The Division also administers the reregistration system for licensed professionals practicing in the State. In order to practice or use a professional title in New York, a professional must be registered as well as licensed. The registration period is specific for each profession and expires for all members of that profession on the date indicated on each practitioner's registration certificate. It is the responsibility of the professional to maintain current registration. It is also the professional's responsibility to notify the Department of any change of address or of name. Only if the Department has current information about the practitioner can the Department provide reregistration materials routinely.

The Division of Professional Licensing Services comprises several units which provide specialized services to professionals and the public, including:

Customer Service Unit - for verification of licensure and registration, certification of New York licensure for other state licensing agencies, and "freedom of information" requests; (518-474-6097). To verify license/registration status (**toll-free for New York State residents only**); 1-800-342-3729.

Registration Unit - for registration problems and changes in data, including name and address. (518-474-3810)

Practitioner Services Unit - for certification of professional service corporations and certain "grandfathered" business corporations. (518-474-8225)

To write to a specific unit within the Division of Professional Licensing Services, letters should be addressed to the attention of that Unit and sent to:

New York State Education Department
Division of Professional Licensing Services
Cultural Education Center
Albany, N.Y. 12230

Professional Discipline

A license permitting an individual to practice in New York State is in effect for the lifetime of the holder unless use of the license is affected by a finding of professional misconduct. Professional misconduct is defined in Section 6509, Education Law, and in Part 29, Rules of the Board of Regents. It is the responsibility of each professional to be aware of the laws and regulations covering his or her profession.

The Office of Professional Discipline, State Education Department, enforces standards of professional conduct in all professions, provided that, in medicine, initial enforcement action is vested in the Office of Professional Medical Conduct, Department of Health. Any person who suspects or has knowledge of professional misconduct should report the information to the appropriate office. (Physicians are required by law to make such reports; failing to do so is, in itself, misconduct.) When either office discovers a possible violation of standards, it starts professional misconduct proceedings. Final disciplinary actions in all professions are taken by the Board of Regents. If the Regents decide that a licensed person has acted unprofessionally, they may suspend or revoke the authorization to practice. The Regents may also impose fines and other appropriate penalties.

Telephone calls or letters reporting professional misconduct will be treated confidentially. To report misconduct, in professions other than medicine:

Write or call the New York State Education Department, Office of Professional Discipline, 622 Third Avenue, New York, NY 10017, 212-557-2100; or call the **Professional Misconduct Hotline:** 1-800-442-8106. The call is toll-free from anywhere in New York State. (On holidays or during nonbusiness hours, you may call and leave a recorded message. Your

call will be returned.) Or call or write the regional office nearest you:

Albany: Office of Professional Discipline, State Education Department, Cultural Education Center, Albany, NY 12230. Telephone: 518-474-3861.

Buffalo: Office of Professional Discipline, 2 Pleasant Avenue West, Lancaster, NY 14086. Telephone: 716-681-2860 or 2861.

Long Island: Office of Professional Discipline, 525 Half Hollow Road, Dix Hills, NY 11746. Telephone: 516-549-2371 or 2321.

Rochester: Office of Professional Discipline, P.O. Box 50, 150 Telephone Road, West Henrietta, NY 14586. Telephone: 716-334-5184 or 5469.

Syracuse/Utica: Office of Professional Discipline, Tecumseh School-Room 11, Nottingham & Waring Road, Jamesville, NY 13078. Telephone: 315-445-2111 or 2112.

White Plains: Office of Professional Discipline, 55 Church Street, White Plains, NY 10601. Telephone: 914-761-8067.

In Medicine, write or call:
Office of Professional Medical Conduct
N.Y.S. Department of Health
Empire State Plaza
Tower Building
Albany, NY 12237
Telephone: 518-474-8357

NATURE OF THE PROFESSION OF PHARMACY

Pharmacy is a professional practice which includes a number of activities which are necessary for the provision of drugs for use by patients pursuant to the orders of persons authorized by State law to prescribe drugs. The essential elements of the practice may be identified as dispensing, counseling and consultation. Dispensing involves the physical acts necessary for the filling of prescriptions and the judgmental processes required for the safety of the patient. Increasingly, pharmacists are employing electronically maintained patient medication histories to assist in judgment-making.

The counseling of patients and consultation with practitioners are carried out whenever, in the judgment of the pharmacist, the welfare of the patient requires.

When authorized, pharmacists select and dispense less expensive therapeutic equivalents of brand name drugs, thus contributing to the containment of health care costs.

AUTHORIZATION TO PRACTICE PHARMACY

Only a person licensed may use the title "pharmacist" or, unless exempt, may legally perform or offer to perform acts which come within the scope of the statutory definition of practice. (Education Law sections 6512, 6513, 6803 and 6811).

A limited permit authorizing practice by a "pharmacy intern" under the immediate and personal supervision of a licensed pharmacist may be issued to advanced pharmacy students and graduates of pharmacy programs (id. section 6806).

Health professionals practicing within the scopes of their respective professions, which scopes include dispensing, are exempt from the licensing requirement (id. sections 6505 and 6807).

The requirements and procedures for obtaining a Pharmacist license are set forth in Section 6805 of the Education Law and in Parts 59 and 63 of the Regulations of the Commissioner of Education.

A licensee must register with the Education Department in order to practice in this State. Registration is accomplished by the submission of an application accompanied by the statutory fee (section 6502 of the Education Law and Part 59 of the Regulations).

Questions relating to the application for admission to the licensing examination or to the triennial registration of pharmacists should be directed to the Division of Professional Licensing Services, Cultural Education Center, Albany, New York 12230.

REGISTRATION OF ESTABLISHMENTS

Registration by the Education Department is required of all persons (individuals, partnerships or corporations) who possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling or manufacturing or who offer such materials for sale at retail or wholesale. The Department registers pharmacies, wholesalers, manufac-

turers and stores (Education Law section 6808 and section 63.6 of the Regulations).

Pharmacies may be owned by unlicensed persons or corporations provided that the actual practice of pharmacy is conducted by licensed pharmacists. A separate registration is required for each pharmacy. A licensed pharmacist must be designated formally as the "supervising pharmacist" for each pharmacy. Such pharmacist is personally responsible for the conduct of the practice of pharmacy at the specified pharmacy and for insuring compliance with all applicable laws, rules and regulations.

The owners of manufacturing and wholesaling establishments are not required to be pharmacists. The supervisors of such establishments must meet requirements stated in the regulations.

Questions relating to the registration of establishments should be directed to:

Board of Pharmacy
The State Education Department
Cultural Education Center
Albany, New York 12230
Telephone: 518-474-7740, 7741

STATUTORY PROVISION

TITLE VIII OF THE EDUCATION LAW
ARTICLE 130: GENERAL PROVISIONS

SUBARTICLE 1. INTRODUCTORY SUMMARY

§ 6500. Introduction

This title provides for the regulation of the admission to and the practice of certain professions. This first article applies to all the professions included in this title, except that prehearing procedures and hearing procedures in connection with the regulation of professional conduct of the profession of medicine shall be conducted pursuant to the provisions of Title II-A of article two of the public health law. Each of the remaining articles applies to a particular profession.

§ 6501. Admission to a profession (licensing)

Admission to practice of a profession in this state is accomplished by a license being issued to a qualified applicant by the education department. To qualify for a license an applicant shall meet the requirements prescribed in the article for the particular profession.

§ 6502. Duration and registration of a license

1. A license shall be valid during the life of the holder unless revoked, annulled or suspended by the board of regents. A licensee must register with the department to practice in this state.
2. The department shall establish the beginning dates of the registration periods for each profession and mail an application for registration to every licensee currently registered at least four months prior to the beginning of the registration period for the respective profession.
3. An application for registration and the required registration fee shall be submitted together with or as a part of the application for a license. A person initially licensed or a licensee resuming practice after a lapse of registration in the last four months of a registration period shall be registered

for the succeeding registration period without an additional registration fee. The department shall renew the registration of each licensee upon receipt of a proper application, on a form prescribed by the department, and the registration fee. Any licensee who fails to register by the beginning of the appropriate registration period shall be required to pay an additional fee for late filing of five dollars for each month that registration has been delayed while such licensee continued to practice his profession. The licensee resuming practice after a lapse of registration shall be permitted to practice without actual possession of the registration certificate for not more than four months after mailing to the department the required application fee.

4. Any licensee who is not engaging in the practice of his profession in this state and does not desire to register shall so advise the department. Such licensee may subsequently register and resume practice without paying an additional fee for failure to register at the beginning of the registration period.

5. Licensees shall notify the department of any change of name or mailing address within thirty days of such change.

§6503. Practice of a profession

Admission to the practice of a profession (1) entitles the licensee to practice the profession as defined in the article for the particular profession, (2) entitles the individual licensee to use the professional title as provided in the article for the particular profession, and (3) subjects the licensee to the procedures and penalties for professional misconduct as prescribed in this article (sections sixty-five hundred nine, sixty-five hundred ten, and sixty- five hundred eleven).

§6504. Regulation of the professions

Admission to the practice of the professions (licensing) and regulation of such practice shall be supervised by the board of regents (section sixty-five hundred six) and administered by the education department (section sixty-five hundred seven), assisted by a state board for each profession (section sixty-five hundred eight).

§6505. Construction

No definition of the practice of a profession shall be construed to restrain or restrict the performance of similar acts authorized in the definition of other professions.

§6505 - a. Professional referrals

There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any association or society of professionals authorized to practice under this title, or any employee, agent, or member thereof, for referring any person to a member of the profession represented by such association or society provided that such referral was made without charge as a service to the public, and without malice, and in the reasonable belief that such referral was warranted, based upon the facts disclosed.

SUBARTICLE 2. STATE MANAGEMENT

§6506. Supervision by the board of regents

The board of regents shall supervise the admission to and the practice of the professions. In supervising, the board of regents may:

1. Promulgate rules;
2. Establish by rule, high school, preprofessional, professional and other educational qualifications required for licensing in the professions regulated by this title;
3. Charter schools offering educational programs for the professions regulated by this title, and no such school shall operate in this state without such a charter, except Columbia University, any school chartered by special act of the legislature prior to September one, nineteen hundred seventy-one, and schools specifically authorized to conduct such programs by the regents;
4. Appoint such committees as it deems necessary and compensate members of such committees who are not members of the board of regents or the department up to one hundred dollars per day for each day devoted to committee functions, together with their necessary expenses;
5. Waive education, experience and examination requirements for a professional license prescribed in the article relating to the profession, provided the board of regents shall be satisfied that the requirements of such article have been substantially met;
6. Indorse a license issued by a licensing board of another state or country upon the applicant fulfilling the following requirements:
    a. Application: file an application with the department;
    b. Education: meet educational requirements in accordance with the commissioner's regulations;
    c. Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;
    d. Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;

e. Age: be at least twenty-one years of age;
f. Citizenship or immigration status: be a United States citizen or an alien lawfully admitted for permanent residence in the United States; and
g. Character: be of good moral character as determined by the department.

7. Direct the department to remedy any error, omission, delay or other circumstance in the issuance or registration of a license;
8. Designate a professional conduct officer, who shall be the chief administrative officer of the office of the professions, or his designee, in connection with professional licensing and misconduct proceedings and criminal matters, such officer to be empowered to issue subpoenas and administer oaths in connection with such proceedings;
9. Establish by rule, standards of conduct with respect to advertising, fee splitting, practicing under a name other than that of the individual licensee (when not specifically authorized), proper use of academic or professional degrees or titles tending to imply professional status, and such other ethical practices as such board shall deem necessary; and
10. Delegate to department officers the disposition of any licensing matters pursuant to rules.

§6507. Administration by the education department

1. The commissioner and the department shall administer the admission to and the practice of the professions.
2. In administering, the commissioner may:
a. Promulgate regulations;
b. Conduct investigations;
c. Issue subpoenas;
d. Grant immunity from prosecution in accordance with section 50.20 of the criminal procedure law to anyone subpoenaed in any investigation or hearing conducted pursuant to this title; and
e. Excuse, for cause acceptable to the commissioner, the failure to register with the department. Such excuse shall validate and authorize such practitioner's right to practice pending registration.

3. The department assisted by the board for each profession, shall:

a. Establish standards for preprofessional and professional education, experience and licensing examinations as required to implement the article for each profession;

b. Review qualifications in connection with licensing requirements; and

c. Provide for licensing examinations and reexaminations.

4. The department shall:

a. Register or approve educational programs designed for the purpose of providing professional preparation which meet standards established by the department.

b. Issue licenses, registrations, and limited permits to qualified applicants;

c. (i) Issue a certificate of authority to a qualified professional service corporation being organized under section fifteen hundred three of the business corporation law on payment of a fee of fifty dollars, (ii) file a certified copy of each certificate of incorporation and amendment thereto within thirty days after the filing of such certificate or amendment on payment of a fee of ten dollars, (iii) file the annual statement required by section fifteen hundred fourteen of the business corporation law on payment of a fee of twenty dollars.

d. Revoke limited permits on the recommendation of the committee on professional conduct for the profession concerned;

e. Maintain public records of licenses issued and retain in its files identifying data concerning each person to whom a license has been issued;

f. Collect the fees prescribed by this title or otherwise provided by law;

g. Prepare an annual report for the legislature, the governor and other executive offices, the state boards for the professions, professional societies, consumer agencies and other interested persons. Such report shall include but not be limited to a

description and analysis of the administrative procedures and operations of the department based upon a statistical summary relating to (i) new licensure, (ii) discipline, (iii) complaint, investigation, and hearing backlog, (iv) budget, and (v) the state boards for the professions. Information provided shall be enumerated by profession; and

h. Establish an administrative unit which shall be responsible for the investigation, prosecution and determination of alleged violations of professional conduct.

5. The commissioner and the department shall perform any other functions necessary to implement this title.

§6508. Assistance by state boards for the professions

1. A board for each profession shall be appointed by the board of regents on the recommendation of the commissioner for the purpose of assisting the board of regents and the department on matters of professional licensing, practice, and conduct. The composition of each board shall be as prescribed in the article relating to each profession. Within each board a committee on licensing may be appointed by the board chairman.

Except as provided in paragraph (a) of this subdivision, the membership of each professional licensing board shall be increased by one member, and each such board shall have at least one public representative who shall be selected by the board of regents from the general public.

a. The membership of the professional licensing boards created under sections sixty-five hundred twenty-three, sixty-eight hundred four, sixty-nine hundred three, and seventy-four hundred three of this chapter shall be increased by two members, and each such board shall have at least two public representatives, who shall be selected by the board of regents from the general public.

b. For the purposes of this title, a "public representative" shall be a person who is a consumer of services provided by those licensed or otherwise supervised or regulated by the boards created hereunder, and shall not be, nor within five years

immediately preceding appointment have been:

(i) a licensee or person otherwise subject to the supervision or regulation of the board to which appointed; or

(ii) a person maintaining a contractual relationship with a licensee of such board, which would constitute more than two percentum of the practice or business of any such licensee, or an officer, director, or representative of such person or group of persons.

2. Each board, or its committee on licensing, shall select or prepare examinations, may conduct oral and practical examinations and reexaminations, shall fix passing grades, and assist the department in other licensing matters as prescribed by the board of regents.

3. Each board shall conduct disciplinary proceedings as prescribed in this article and shall assist in other professional conduct matters as prescribed by the board of regents.

4. Members of each board shall be appointed by the board of regents for five-year terms except that the terms of those first appointed shall be arranged so that as nearly as possible an equal number shall terminate annually. A vacancy occurring during a term shall be filled by an appointment by the board of regents for the unexpired term. Each state professional association or society may nominate one or more candidates for each appointment to be made to the board for its profession, but the board of regents shall not be required to appoint candidates so nominated. Former members of a board may be re-appointed by the board of regents, on the recommendation of the commissioner, to serve as members of the board solely for the purposes of disciplinary proceedings, proceedings relating to the moral character of an applicant for licensure, and proceedings relating to applications for the restoration of a professional license. Former board members so appointed may not comprise a majority of any panel.

5. Each member of a board shall receive a certificate of appointment, shall before beginning his term of office file a constitutional oath of office with the secretary of state, shall receive up to one hundred dollars as prescribed by the board of regents for each day devoted to board work, and shall be reimbursed for his necessary expenses. No member shall

serve beyond the age of seventy. Any member may be removed from a board by the board of regents for misconduct, incapacity or neglect of duty.

6. Each board shall elect from its members a chairman and vice-chairman annually, shall meet upon call of the chairman or the department, and may adopt bylaws consistent with this title and approved by the board of regents. A quorum for the transaction of business by the board shall be a majority of members but not less than five members.

7. An executive secretary to each board shall be appointed by the board of regents on recommendation of the commissioner. Such executive secretary shall not be a member of the board, shall hold office at the pleasure of, and shall have the powers, duties and annual salary prescribed by the board of regents.

SUBARTICLE 3. PROFESSIONAL MISCONDUCT

§ 8509. Definitions of professional misconduct

Each of the following is professional misconduct, and any licensee found guilty of such misconduct under the procedures prescribed in section sixty-five hundred ten shall be subject to the penalties prescribed in section sixty-five hundred eleven:

1. Obtaining the license fraudulently,
2. Practicing the profession fraudulently, beyond its authorized scope, with gross incompetence, with gross negligence on a particular occasion or negligence or incompetence on more than one occasion,
3. Practicing the profession while the ability to practice is impaired by alcohol, drugs, physical disability, or mental disability,
4. Being habitually drunk or being dependent on, or a habitual user of narcotics, barbiturates, amphetamines, hallucinogens, or other drugs having similar effects,
5. a. Being convicted of committing an act constituting a crime under:
   (i) New York State law or,
   (ii) Federal law or,
   (iii) The law of another jurisdiction and which, if committed within this state, would have constituted a crime under New York State law;
   b. Having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York state, constitute professional misconduct under the laws of New York state;
   c. Having been found by the commissioner of health to be in violation of article thirty-three of the public health law.
6. Refusing to provide professional service to a person because of such person's race, creed, color, or national origin,
7. Permitting, aiding or abetting an unlicensed person to perform activities requiring a license,

8. Practicing the profession while the license is suspended, or wilfully failing to register or notify the department of any change of name or mailing address, or if a professional service corporation wilfully failing to comply with sections fifteen hundred three and fifteen hundred fourteen of the business corporation law,

9. Committing unprofessional conduct, as defined by the board of regents in its rules or by the commissioner in regulations approved by the board of regents,

10. A willful violation by a licensed physician of subdivision eleven of section two hundred thirty of the public health law, or

11. A violation of section twenty-eight hundred three-d of the public health law.

§6509 - a. Additional definition of professional misconduct; limited application

Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the license or registration of a person subject to the provisions of articles one hundred thirty-one, one hundred thirty-one-a, one hundred thirty-two, one hundred thirty-three, one hundred thirty-seven, one hundred thirty-nine, one hundred forty- one, one hundred forty-three, one hundred forty-four, one hundred fifty-six and one hundred fifty-nine of this chapter may be revoked, suspended or annulled or such person may be subject to any other penalty provided in section sixty-five hundred eleven of this article in accordance with the provisions and procedure of this article for the following:

That any person subject to the above enumerated articles, has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly requested, received or profited by means of a credit of other valuable consideration as a commission, discount or gratuity in connection with the furnishing of professional care, or service, including x-ray examination and treatment, or for or in connection with the sale, rental, supplying or furnishing of clinical laboratory services or supplies, x-ray laboratory services or supplies, inhalation

therapy service or equipment, ambulance service, hospital or medical supplies, physiotherapy or other therapeutic service or equipment, artificial limbs, teeth or eyes, orthopedic or surgical appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, drugs, medication or medical supplies or any other goods, services or supplies prescribed for medical diagnosis, care or treatment, under this chapter, except payment, not to exceed thirty-three and one-third per centum of any fee received for x-ray examination, diagnosis or treatment, to any hospital furnishing facilities for such examination, diagnosis or treatment. Nothing contained in this section shall prohibit such persons from practicing as partners, in groups or as a professional corporation nor from pooling fees and moneys received, either by the partnerships, professional corporations or groups by the individual members, thereof, for professional services furnished by any individual professional member, or employee of such partnership, corporation or group, nor shall the professionals constituting the partnerships, corporation or groups be prohibited from sharing, dividing or apportioning the fees and moneys received by them or by the partnership, corporation or group in accordance with a partnership or other agreement; provided that no such practice as partners, corporations or in groups or pooling of fees or moneys received or shared, division or apportionment of fees shall be permitted with respect to care and treatment under the workmen's compensation law except as expressly authorized by the workmen's compensation law. Nothing contained in this chapter shall prohibit a medical or dental expense indemnity corporation pursuant to its contract with the subscriber from prorationing a medical or dental expense indemnity allowance among two or more professionals in proportion to the services rendered by each such professional at the request of the subscriber, provided that prior to payment thereof such professionals shall submit both to the medical or dental expense indemnity corporation and to the subscriber statements itemizing the services rendered by each such professional and the charges therefor.

§6510. Proceedings in cases of professional misconduct

In cases of professional misconduct the proceedings shall be as follows:

1. Preliminary procedures.
   a. Complaint. A complaint of a licensee's professional misconduct may be made by any person to the education department.
   b. Investigation. The department shall investigate each complaint which alleges conduct constituting professional misconduct. The results of the investigation shall be referred to the professional conduct officer designated by the board of regents pursuant to section sixty-five hundred six of this article. If such officer decides that there is not substantial evidence of professional misconduct or that further proceedings are not warranted, no further action shall be taken. If such officer, after consultation with a professional member of the applicable state board for the profession, determines that there is substantial evidence of professional misconduct, and that further proceedings are warranted, such proceedings shall be conducted pursuant to this section. If the complaint involves a question of professional expertise, then such officer may seek, and if so shall obtain, the concurrence of at least two members of a panel of three members of the applicable board.
   c. Charges. In all disciplinary proceedings other than those terminated by an administrative warning pursuant to paragraph a of subdivision two of this section, the department shall prepare the charges. The charges shall state the alleged professional misconduct and shall state concisely the material facts but not the evidience (sic) by which the charges are to be proved.
   d. Service of charges and of notice of hearing. A copy of the charges and notice of any hearing pursuant to subdivision two or three of this section shall be served on the licensee personally by the department at least fifteen days before the hearing. If personal service cannot be made after due diligence and such fact is certified under oath, a copy of the charges and the notice of hearing shall be served by certified mail, return receipt requested

to the licensee's last known address by the department at least twenty days before the hearing.

2. Expedited procedures.

a. Violations. Violations involving professional misconduct of a minor or technical nature may be resolved by expedited procedures as provided in paragraph b or c of this subdivision. For purposes of this subdivision, violations of a minor or technical nature shall include, but shall not be limited to, isolated instances of violations concerning professional advertising or record keeping, and other isolated violations which do not directly affect or impair the public health, welfare or safety. The board of regents shall make recommendations to the legislature on or before June first, nineteen hundred eighty-one, for the further definition of violations of a minor or technical nature. The initial instance of any violation of a minor or technical nature may be resolved by the issuance of an administrative warning pursuant to paragraph b of this subdivision. Subsequent instances of similar violations of a minor or technical nature within a period of three years may be resolved by the procedure set forth in paragraph c of this subdivision.

b. Administrative warning. If a professional conduct officer, after consultation with a professional member of the state board, determines that there is substantial evidence of professional misconduct but that it is an initial violation of a minor or technical nature which would not justify the imposition of a more severe disciplinary penalty, the matter may be terminated by the issuance of an administrative warning. Such warnings shall be confidential and shall not constitute an adjudication of guilt or be used as evidence that the licensee is guilty of the alleged misconduct. However, in the event of a further allegation of similar misconduct by the same licensee, the matter may be reopened and further proceedings instituted as provided in this section.

c. Determination of penalty on uncontested minor violations. If a professional conduct officer, after consultation with a professional member of the state board, determines that there is substantial evidence of a violation of a minor or technical nature, and of a nature justifying a penalty as specified in this paragraph, the department may prepare and serve charges either by personal service or by certified mail, return receipt requested. Such charges shall include a statement that unless an answer is received within twenty days denying the charges, the matter shall be referred to a violations committee consisting of five members of the state board for the profession, at least one of whom shall be a public representative for determination. The violations panel shall be appointed by the executive secretary of the state board. The licensee shall be given at least fifteen days notice of the time and place of the meeting of the violations committee and shall have the right to appear in person and by an attorney and to make a statement to the committee in mitigation or explanation of the misconduct. The department may appear and make a statement in support of its position. The violations committee may issue a censure and reprimand, and in addition, or in the alternative, may impose a fine not to exceed five hundred dollars for each specification of minor, or technical misconduct. If the fine is not paid within three months the matter may be reopened and shall be subject to the hearing and regents decision procedures of this section. The determination of the panel shall be final and shall not be subject to the regents decision procedures of this section. If an answer is filed denying the charges, the matter shall be processed as provided in subdivision three of this section.

d. Convictions of crimes or administrative violations. In cases of professional misconduct based solely upon a violation of subdivision five of section sixty-five hundred nine of this article, the professional conduct officer may prepare and serve the charges

and may refer the matter directly to a regents review committee for its review and report of its findings, determination as to guilt, and recommendation as to the measure of discipline to be imposed. In such cases the notice of hearing shall state that the licensee may file a written answer or brief; that the licensee may appear personally before the regents review committee and may be represented by counsel, and the notice may contain such other information as may be considered appropriate by the department. In lieu of referring the matter to the board of regents, the regents review committee may refer any such matter for further proceedings pursuant to paragraph b or c of this subdivision or subdivision three of this section.

3. Adversary proceedings. Contested disciplinary proceedings and other disciplinary proceedings not resolved pursuant to subdivision two of this section shall be tried before a hearing panel of the appropriate state board as provided in this subdivision.

a. Notice of hearing. The department shall set the time and place of the hearing and shall prepare the notice of hearing. The notice of hearing shall state (1) the time and place of the hearing, (2) that the licensee may file a written answer to the charges prior to the hearing, (3) that the licensee may appear personally at the hearing and may be represented by counsel, (4) that the licensee shall have the right to produce witnesses and evidence in his behalf, to cross-examine witnesses and examine evidence produced against him, and to issue subpoenas in accordance with the provisions of the civil practice law and rules, (5) that a stenographic record of the hearing will be made, and (6) such other information as may be considered appropriate by the department.

b. Hearing panel. The hearing shall be conducted by a panel of five or more members of the applicable state board for the profession, at least one of whom shall be a public representative. The executive secretary for the applicable state board shall appoint

the panel and shall designate its chairperson. In addition to said panel members, the department shall designate an administrative officer, admitted to practice as an attorney in the state of New York, who shall have the authority to rule on all motions, procedures and other legal objections and shall draft a report for the hearing panel which shall be subject to the approval of and signature by the panel chairperson on behalf of the panel. The administrative officer shall not be entitled to a vote.

c. Conduct of hearing. The evidence in support of the charges shall be presented by an attorney for the department. The licensee shall have the rights required to be stated in the notice of hearing. The panel shall not be bound by the rules of evidence, but its determination of guilt shall be based on substantial legal evidence. A hearing which has been initiated shall not be discontinued because of the death or incapacity to serve of one member of the hearing panel.

d. Results of hearing. The hearing panel shall render a written report which shall include (1) findings of fact, (2) a determination of guilty or not guilty on each charge, and (3) in the event of a determination of guilty, a recommendation of the penalty to be imposed. For the panel to make a determination of guilty, a minimum of four of the voting members of the panel must vote for such a determination. A copy of the report of the hearing panel shall be transmitted to the licensee.

4. Regents decision procedures.

a. Regents review committee. The transcript and report of the hearing panel shall be reviewed at a meeting by a regents review committee appointed by the board of regents. The regents review committee shall consist of three members, at least one of whom shall be a regent.

b. Regents review committee meetings. The review shall be based on the transcript and the report of the hearing panel. The licensee may appear at the meeting, and the regents review committee may

require the licensee to appear. The licensee may be represented by counsel. The department shall notify the licensee at least seven days before the meeting (1) of the time and place of the meeting, (2) of his right to appear, (3) of his right to be represented by counsel, (4) whether or not he is required to appear, and (5) of such other information as may be considered appropriate. After the meeting, the regents review committee shall transmit a written report of its review to the board of regents. In cases referred directly to the regents review committee pursuant to paragraph d of subdivision two of this section, the review shall be based upon the charges, the documentary evidence submitted by the department, and any answer, affidavits or brief the licensee may wish to submit.

c. Regents decision and order. The board of regents (1) shall consider the transcript, the report of the hearing panel, and the report of the regents review committee, (2) shall decide whether the licensee is guilty or not guilty on each charge, (3) shall decide what penalties, if any, to impose as prescribed in section sixty-five hundred eleven of this article, and (4) shall issue an order to carry out its decisions. Such decisions shall require the affirmative vote of a majority of the members of the board of regents. If the board of regents disagrees with the hearing panel's determination of not guilty, it shall remand the matter to the original panel for reconsideration or to a new panel for a new hearing. The panel's determination of not guilty on reconsideration or a new hearing shall be final. The order shall be served upon the licensee personally or by certified mail to the licensee's last known address and such service shall be effective as of the date of the personal service or five days after mailing by certified mail. The licensee shall deliver to the department the license and registration certificate which has been revoked, annulled, suspended, or surrendered within five days after the effective date of the service of the order. If the license or registra-

tion certificate is lost, misplaced or its whereabouts is otherwise unknown, the licensee shall submit an affidavit to that effect, and shall deliver such license or certificate to the department when located.

5. Court review procedures. The decisions of the board of regents may be reviewed pursuant to the proceedings under article seventy-eight of the civil practice law and rules. Such proceedings shall be returnable before the appellate division of the third judicial department, and such decisions shall not be stayed or enjoined expect upon application to such appellate division after notice to the department and to the attorney general and upon a showing that the petitioner has a substantial likelihood of success.

6. The provisions of subdivisions one through four of this section shall not be applicable to proceedings in cases of professional misconduct involving the medical profession.

7. Notwithstanding any other provisions of the law, persons who assist the department as consultants or expert witnesses in the investigation or prosecution of alleged professional misconduct, licensure matters, restoration proceedings, or criminal prosecutions for unauthorized practice, shall not be liable for damages in any civil action or proceeding as a result of such assistance, except upon proof of actual malice. The attorney general shall defend such persons in any such action or proceeding, in accordance with section seventeen of the public officers law.

8. The files of the department relating to the investigation of possible instances of professional misconduct, or the unlawful practice of any profession licensed by the board of regents, or the unlawful use of a professional title or the moral fitness of an applicant for a professional license or permit, shall be confidential and not subject to disclosure at the request of any person, except upon the order of a court in a pending action or proceeding. The provisions of this subdivision shall not apply to documents introduced in evidence at a hearing held pursuant to this chapter and shall not prevent the department from sharing information concerning investigations with other duly authorized public agencies responsible for professional regulation or criminal prosecution.

§6510a. Proceedings in cases of professional misconduct involving the medical profession

1. Prehearing procedures, hearing procedures and summary action procedures. Prehearing procedures, hearing procedures and summary action procedures in cases of professional misconduct involving the medical profession shall be conducted pursuant to the provisions of Title II-A of article two of the public health law.

2. Regents decision and order. Within sixty days of the transfer of a case of professional misconduct involving the medical profession by the commissioner of health pursuant to section two hundred thirty of the public health law, the board of regents (a) shall consider the transcript, exhibits and other evidence, if any, the findings, conclusions and recommendation of the committee on professional misconduct and the recommendation of the commissioner of health, (b) shall decide whether the licensee is guilty or not guilty on each charge, (c) shall decide what penalties, if any, to impose as prescribed in section sixty-five hundred eleven of this article, and (d) shall issue an order to carry out its decisions. Such decisions shall require the affirmative vote of a majority of the members of the board.

3. Time limitations.

a. No failure to comply with a provision of this section requiring that a specified action shall be taken within a specified period of time shall affect the validity of the action taken.

b. The time limitations specified in this section for the completion of specified actions may be extended, upon application of a licensee or his attorney, for good cause shown, upon application made prior to the expiration of such time limitations.

4. Court review procedures. The decisions of the board of regents may be reviewed pursuant to the proceedings under article seventy-eight of the civil practice law and rules. Such proceedings shall be returnable before the appellate division of the third judicial department, and such decisions shall not be stayed or enjoined except upon application to such appellate division after notice to the attorney general.

§6511. Penalties for professional misconduct

The penalties which may be imposed by the board of regents on a present or former licensee found guilty of professional misconduct (under the definitions and proceedings prescribed in sections sixty-five hundred nine, sixty-five hundred ten and sixty-five hundred ten-a of this article) are: (1) censure and reprimand, (2) suspension of license, (a) wholly, for a fixed period of time; (b) partially, until the licensee successfully completes a course of retraining in the area to which the suspension applies; (c) wholly, until the licensee successfully completes a course of therapy or treatment prescribed by the regents; (3) revocation of license, (4) annulment of license or registration, (5) limitation on registration or issuance of any further license, (6) a fine not to exceed ten thousand dollars, upon each specification of charges of which the respondent is determined to be guilty, (7) a requirement that a licensee pursue a course of education or training, and (8) a requirement that a licensee perform up to one hundred hours of public service, in a manner and at a time and place as directed by the board. The board of regents may stay such penalties in whole or in part, may place the licensee on probation and may restore a license which has been revoked. Any fine imposed pursuant to this section or pursuant to subdivision two of section sixty-five hundred ten of this article may be sued for and recovered in the name of the people of the state of New York in an action brought by the attorney general. In such action the findings and determination of the board of regents or of the violations committee shall be admissible evidence and shall be conclusive proof of the violation and the penalty assessed.

SUBARTICLE 4. UNAUTHORIZED ACTS

§6512. Unauthorized practice a crime

1. Anyone not authorized to practice under this title who practices or offers to practice or holds himself out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who practices any profession as an exempt person during the time when his professional license is suspended, revoked or annulled, or who aids or abets an unlicensed person to practice a profession, or who fraudulently sells, files, furnishes, obtains, or who attempts fraudulently to sell, file, furnish or obtain any diploma, license, record or permit purporting to authorize the practice of a profession, shall be guilty of a class E felony.

2. Anyone who knowingly aids or abets three or more unlicensed persons to practice a profession or employs or holds such unlicensed persons out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who knowingly aids or abets three or more persons to practice any profession as exempt persons during the time when the professional licenses of such persons are suspended, revoked or annulled, shall be guilty of a class E felony.

§6513. Unauthorized use of a professional title a crime

1. Anyone not authorized to use a professional title regulated by this title, and who uses such professional title, shall be guilty of a class A misdemeanor.

2. Anyone who knowingly aids or abets three or more persons not authorized to use a professional title regulated by this title, to use such professional title, or knowingly employs three or more persons not authorized to use a professional title regulated by this title, who use such professional title in the course of such employment, shall be guilty of a class E felony.

§6514. Criminal proceedings

1. All alleged violations of sections sixty-five hundred twelve or sixty-five hundred thirteen of this article shall be

reported to the department which shall cause an investigation to be instituted. If the investigation substantiates that violations exist, such violations shall be reported to the attorney general with a request for prosecution.

2. The attorney general shall prosecute such alleged offenses in the name of the state, provided, however, in the event of alleged violations of article one hundred fifty-five of this title occurring in cities with a population of one million or more, a district attorney may prosecute such alleged offenses in the name of the state provided, however, that any district attorney may prosecute such offenses where they are incidental to a criminal prosecution instituted by him under other statutes.

3. All criminal courts having jurisdiction over misdemeanors are hereby empowered to hear, try and determine alleged violations under this title, which constitute misdemeanors, without indictment and to impose applicable punishment of fines or imprisonments or both. It shall be necessary to prove in any prosecution under this title only a single prohibited act or a single holding out without proving a general course of conduct.

4. A proceeding before a committee on professional conduct shall not be deemed to be a criminal proceeding within the meaning of this section.

§6515. Restraint of unlawful acts

Where a violation of this title is alleged to have occurred, the attorney general or, in the event of alleged violations of article one hundred fifty-five of this title occurring in cities having a population of one million or more, the corporation counsel may apply to the supreme court within the judicial district in which such violation is alleged to have occurred for an order enjoining or restraining commission or continuance of the unlawful acts complained of. The court shall have jurisdiction of the proceedings and shall have power to grant such temporary relief or restraining order as it deems just and proper. In any such proceeding it shall be unnecessary to allege or prove that an adequate remedy at law does not exist or that irreparable damage would result if such order were not granted. The remedy provided in this section shall be in addition to any other remedy provided by law or to the proceedings commenced against a licensee under this title.

ARTICLE 137

PHARMACY

§6800. Introduction. This article applies to the profession of pharmacy. The general provisions for all professions contained in article one hundred thirty of this title apply to this article.

§6801. Definition of practice of pharmacy. The practice of the profession of pharmacy is defined as the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority.

§6802. Definitions. 1. "Pharmacy" means any place, other than a registered store, in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

2. "Registered store" means a store for which a storekeeper's license has been issued, located in a village or place of less than one thousand inhabitants that has no pharmacy within three miles.

3. "Formulary" means the latest edition of the official national formulary, and its supplement.

4. "Pharmacopeia," when not otherwise limited, means the latest edition of the official United States pharmacopeia, and its supplement.

5. "Homeopathic pharmacopeia" means the official homeopathic pharmacopeia of the United States, and its supplement.

6. "Official compendium" means the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary or their supplements.

7. "Drugs" means:

a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.

b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.

c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.

d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

8. "Cosmetics" means:

a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

b. Articles intended for use as a component of any such articles; except that the term shall not include soap.

9. "Poison," where not otherwise limited, means any drug, chemical or preparation likely to be destructive to adult human life in quantity of sixty grains or less.

10. "Label" means a display of written, printed or pictorial matter upon the immediate container of any drug, device or cosmetic. Any requirement made by or under authority of this article, that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there be any, of the retail package of such drug, device or cosmetic or is easily legible through the outside container or wrapper.

11. "Immediate container" does not include package liners.

12. "Labeling" means all labels and other written, printed or pictorial matter:

a. Upon any drug, device or cosmetic or any of its containers or wrappers, or

b. Accompanying such drug, device or cosmetic.

13. "Misbranding." A drug, device or cosmetic is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with re-

spect to consequences which may result from the use of the drug, device, or cosmetic to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. No drug, device or cosmetic which is subject to, and complies with regulations promulgated under the provisions of the federal food, drug, and cosmetic act, relating to adulteration and misbranding shall be deemed to be adulterated or misbranded in violation of the provisions of this article because of its failure to comply with the board's regulations, or the rules of the state board of pharmacy, insofar as the regulations are in conflict with regulations relating to adulteration and misbranding under the federal food, drug and cosmetic act.

14. "Antiseptic." The representation of a drug, device or cosmetic in its labeling, as an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

15. "New drug" means:

a. Any drug not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested by the drug's labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to September first, nineteen hundred thirty-nine it was subject to the former federal food and drug act of June thirtieth, nineteen hundred six, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become recognized, but which has not otherwise than in such investigations been used to a material extent or for a material time under such conditions.

16. "Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:

a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or

b. To affect the structure or any function of the body of man or animals.

17. The term "Federal Food, Drug and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June twenty-fifth, nineteen hundred thirty-eight, officially cited as public document number seven hundred seventeen- seventy-fifth congress (chapter six hundred seventy-five--third session), and all its amendments now or hereafter enacted.

18. "Wholesaler" means a person who bottles, packs or purchases drugs, devices or cosmetics for the purpose of selling or reselling to pharmacies or to other channels as provided in this article.

19. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics.

20. "Controlled substance" means any drug defined as a controlled substance by article thirty-three of the public law.

21. "Manufacturer" means a person who compounds, mixes, prepares, produces, and bottles or packs drugs, cosmetics or devices for the purpose of distributing or selling to pharmacies or to other channels of distribution.

§6803. Practice of pharmacy and use of title "pharmacist." Only a person licensed or otherwise authorized under this article shall practice pharmacy or use the title "pharmacist" or any derivative.

§6804. State board of pharmacy. A state board of pharmacy shall be appointed by the regents on recommendation of the commissioner for the purpose of assisting the regents and the department on matters of professional licensing and professional conduct in accordance with section sixty-five hundred eight of this title. The board shall be composed of not less than nine pharmacists licensed in this state for at least five years. An executive secretary to the board shall be appointed by the regents on recommendation of the commissioner and shall be a pharmacist licensed in this state for at least five years. The board shall have power:

a. To regulate the practice of pharmacy and the employment of interns and employees in pharmacies,

b. To regulate and control the sale, distribution, character and standard of drugs, poisons, cosmetics, devices and new drugs,

c. To employ inspectors and chemists,

d. To prevent the sale or distribution of such drugs, poisons, cosmetics, devices and new drugs as do not conform to the provisions of this article or of the public health law,

e. To investigate alleged violations of the provisions of this article through its own investigative personnel or those of other agencies, to conduct hearings, to levy money penalties, and to bring alleged violations to the notice of the attorney general, and

f. To issue limited permits or registrations.

§6805. Requirements for a professional license. 1. To qualify for a pharmacist's license, an applicant shall fulfill the following requirements:

(1) Application: file an application with the department;

(2) Education: have received an education, including a bachelor's or equivalent degree in pharmacy, in accordance with the commissioner's regulations;

(3) Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;

(4) Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;

(5) Age: be at least twenty-one years of age;

(6) Citizenship or immigration status: be a United States citizen or an alien lawfully admitted for permanent residence in the United States;

(7) Character: be of good moral character as determined by the department; and

(8) Fees: pay a fee of one hundred dollars to the department for admission to a department conducted examination and for an initial license, a fee of fifty dollars for each re-examination, a fee of sixty-five dollars for an initial license for persons not requiring admission to a department conducted examination, and a fee of sixty dollars for the biennial registration period ending December thirty-first, nineteen hundred eighty-two, and a fee of ninety dollars for each triennial registration period

commencing on and after January first, nineteen hundred eighty-three.

2. On or before April first, nineteen hundred seventy-two, any person who holds a valid license as "druggist" in this state shall make application and on the payment of fees specified in this title be licensed by the department as a pharmacist. Such person shall have all of the rights, privileges, duties and responsibilities of a pharmacist.

§6806. **Limited permits.** 1. The department may issue a limited permit for employment as a "pharmacy intern" to:

a. A student enrolled in the last two years of a registered program in pharmacy, or

b. A graduate of a program in pharmacy which meets standards established by the commissioner's regulations who is engaged in meeting the experience requirements or whose application for initial licensure is pending with the department.

2. A pharmacy intern may, as determined by the commissioner's regulations, practice as a pharmacist under the immediate personal supervision of a licensed pharmacist.

3. A limited permit issued to a pharmacy intern shall have an expiration date of five years from the date of issue. Limited permits may be renewed once for a period not to exceed two years.

4. Fees. The fee for each limited permit issued to a pharmacy intern shall be forty dollars.

§6807. **Exempt persons.** 1. This article shall not be construed to affect or prevent:

a. Unlicensed assistants from being employed in licensed pharmacies for purposes other than the practice of pharmacy;

b. Any physician, dentist or veterinarian who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, from supplying his patients with such drugs as the physician, dentist or veterinarian deems proper in connection with his practice, provided, however, that all such drugs shall be dispensed in a container labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person is-

suing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label; provided further that if such drugs are controlled substances, they shall be dispensed pursuant to the requirements of article thirty-three of the public health law;

c. Any merchant from selling proprietary medicines, except those which are poisonous, deleterious or habit forming, or materials and devices specifically exempted by regulations of the department or by the public health law;

d. Any personnel in an institution of higher learning from using prescription-required drugs on the premises for authorized research, experiments or instruction, in accordance with the department's regulations and, if such drugs are controlled substances, in accordance with Title III of article thirty-three of the public health law; or

e. The necessary and ordinary activities of manufacturers and wholesalers, subject to the provisions of article thirty-three of the public health law.

§6808. Registering and operating establishments. 1. No person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling, or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the department as a pharmacy, store, wholesaler, or manufacturer.

2. Pharmacies.

a. Obtaining a registration. A pharmacy shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of two hundred dollars.

(3) To secure and retain a registration, a pharmacy must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding and dispensing of prescriptions, as prescribed by regulation.

b. Renewal of registration. All pharmacy registrations shall be renewed in the month of January following the expiration of

the previous registration. The registration application shall be accompanied by a fee of one hundred dollars for the biennial registration period ending December thirty-first, nineteen hundred eighty-three, and a fee of one hundred fifty dollars for each triennial registration period commencing on and after January first, nineteen hundred eighty-four. At the time of renewal, the owner of every pharmacy shall report under oath to the department any facts required by the board of pharmacy.

c. Display of registration. The registration shall be conspicuously displayed at all times in the pharmacy. The names of the owner or owners of a pharmacy shall be conspicuously displayed upon the exterior of such establishment. The names so displayed shall be presumptive evidence of ownership of such pharmacy by such person or persons. In the event that the owner of a licensed pharmacy is not a licensed pharmacist, the pharmacy registration issued shall also bear the name of the licensed pharmacist having personal supervision of the pharmacy. In the event that such licensed pharmacist shall no longer have personal supervision of the pharmacy, the owner shall notify the department of such fact and of the name of the licensed pharmacist replacing the pharmacist named on the license and shall apply for an amended registration showing the change. The amended registration must be attached to the original registration and displayed in the same manner. Both the owner and the supervising pharmacist shall be responsible for carrying out the provision of this article.

d. Change of location. In the event that the location of a pharmacy shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be thirty dollars, unless it appears to the satisfaction of the department that the change in location is of temporary nature due to fire, flood or other disaster.

e. Conduct of a pharmacy. Every owner of a pharmacy is responsible for the strength, quality, purity and the labeling thereof of all drugs, toxic substances, devices and cosmetics, dispensed or sold, subject to the guaranty provision of this article and the public health law. Every owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy. Every pharmacy shall be under the immediate supervision and management of a li-

censed pharmacist at all hours when open. No pharmacist shall have personal supervision of more than one pharmacy at the same time.

f. A pharmacy as a department. When a pharmacy is operated as a department of a larger commercial establishment, the area comprising the pharmacy shall be physically separated from the rest of the establishment, so that access to the pharmacy and drugs is not available when a pharmacist is not on duty. Identification of the area within the pharmacy by use of the words "drugs", "medicines", "drug store", or "pharmacy" or similar terms shall be restricted to the area licensed by the department as a pharmacy.

g. Limited pharmacy registration. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a hospital, nursing home or extended care facility which does not meet all of the requirements for registration as a pharmacy, the department may waive any requirements pertaining to full-time operation by a licensed pharmacist, minimum equipment, minimum space and waiting area, provided that when the waiver of any of the above requirements is granted by the board, the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing drugs to patients registered for treatment by the hospital, and to in-patients for treatment by the nursing home or extended care facility. The initial registration fee and renewal fee for a limited pharmacy shall be fifty dollars for the biennial registration period ending December thirty-first, nineteen hundred eighty-three and seventy-five dollars for each triennial registration period commencing on and after January first, nineteen hundred eighty-four.

3. Registered store.

a. Obtaining a storekeeper's certificate. A registered store shall be licensed by the issuance of a storekeeper's certificate as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of thirty dollars.

(3) No new certificate shall be issued to a store located within six miles of a registered pharmacy.

(4) The certificate may restrict the registered store to the sale of certain pre- packaged drugs as indicated on the certificate.

b. Renewal of certificate. All storekeeper's certificates shall be renewed. The application shall be accompanied by a fee of thirty dollars for the biennial registration period ending December thirty-first, nineteen hundred eighty-three and a fee of forty-five dollars for each triennial registration period commencing on and after January first, nineteen hundred eighty-four.

c. Termination of certificate. Any storekeeper's certificate may be terminated whenever a licensed pharmacy is established within a six-mile radius.

d. Change of location. In the event that the location of the store is changed, the owner must apply for a new certificate.

4. Wholesaler's or manufacturer's registration.

a. Obtaining a registration. A wholesaler or manufacturer shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of five hundred dollars.

b. Renewal of registration. All wholesalers' and manufacturers' registrations shall be renewed in the month of September following the expiration of the previous registration, at a fee of two hundred dollars for each place of business for the biennial registration period ending August thirty-first, nineteen hundred eighty-three and a fee of three hundred dollars for each triennial registration period commencing on and after September first, nineteen hundred eighty-three.

c. Display of registration. The registration shall be displayed conspicuously at all times in the place of business.

d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be one hundred dollars unless it appears to the satisfaction of the department that the change in location is of a temporary nature due to fire, flood or other disaster.

5. Inspection. The state board of pharmacy and the department of education, and their employees designated by the commissioner, shall have the right to enter any pharmacy, wholesaler, manufacturer, or registered store, or vehicle and to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all records required by this article, pertinent equipment, finished and unfinished materials, containers, and labels.

6. Revocation or suspension. A pharmacy, store, wholesaler, or manufacturer registration may be revoked or suspended by the committee on professional conduct of the state board of pharmacy in accordance with the provisions of article one hundred thirty.

7. Sale of drugs at auction. No controlled substance or substances and no poisonous or deleterious drugs or drugs in bulk or in opened containers shall be sold at auction unless the place where such drugs are sold at auction shall have been registered by the board, and unless such sale shall be under the personal supervision of a licensed pharmacist. Drugs in open containers shall not be sold at auction unless the seller shall have in his possession a certificate of the board showing that such drugs have been inspected and meet the requirements of this article. In the event that the drug so sold is one as to which this article or any federal statute or any regulation adopted pursuant to this article or an applicable federal statute require that the expiration date be stated on each package, such drug may not be sold at auction after such expiration date or when such expiration date will occur within a period of thirty days or less from the date of sale.

§6808-a. Identification of pharmacists. Every pharmacist on duty shall be identified by a badge designed by the state board of pharmacy, which shall contain his name and title.

6809. Monetary penalties. Repealed.

§6810. Prescriptions. 1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such

drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision.

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

3. A copy of a prescription for a controlled substance shall not be furnished to the patient but may be furnished to any licensed practitioner authorized to write such prescription. Copies of other prescriptions shall be furnished to the patient at his request, but such copies are issued for the informational purposes of the prescribers only, and shall be so worded.

4. Oral prescriptions for controlled substances shall be filled pursuant to article thirty-three of the public health law. A pharmacist may fill an oral prescription for a drug, other than a controlled substance, made by a practitioner legally authorized to prescribe drugs. An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription. Records of prescriptions for controlled substances shall be maintained pursuant to requirements of article thirty-three of the public health law.

6. (a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing two lines for the prescriber's signature. There shall be a signature line in the lower right hand corner of the prescription form beneath which shall be clearly imprinted the words "substitution permissible"; there shall be a signature line in the lower left hand corner of the prescription form beneath which shall be clearly imprinted the words "dispense as written". The prescriber's signature on either signature line shall validate the prescription and shall designate approval or disapproval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. Imprinted conspicuously on the prescription forms shall be the words: "This prescription will be filled generically unless prescriber signs on line stating 'dispense as written'."

(b) If the prescriber designates approval of substitution he shall inform the patient that the pharmacist will substitute a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law.

(c) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

7. (a) No prescription for a controlled substance written in this state by a person authorized to issue such prescription shall be on a prescription form which authorizes the dispensing or compounding of any other drug or controlled substance. No controlled substance shall be dispensed by a pharmacist when such prescription form includes any other drug or more than one controlled substance.

(b) For the purpose of this subdivision, "controlled substance" means any substance listed in schedule I, II, III, IV or V of section thirty-three hundred six of the public health law.

§6811. Misdemeanors. It shall be a class A misdemeanor for:

1. Any person knowingly or intentionally to prevent or refuse to permit any board member or department representative to enter a pharmacy or any other establishment for the purpose of lawful inspection;

2. Any person whose license has been revoked to refuse to deliver the license;

3. Any pharmacist to display his license or permit it to be displayed in a pharmacy of which he is not the owner or in which he is not employed, or any owner to fail to display in his pharmacy the license of the pharmacist employed in said pharmacy;

4. Any holder of a license to fail to display the license;

5. Any owner of a pharmacy to display or permit to be displayed in his pharmacy the license of any pharmacist not employed in said pharmacy;

6. Any person to carry on, conduct or transact business under a name which contains as a part thereof the words "drugs", "medicines", "drug store", "apothecary", or "pharmacy", or similar terms or combination of terms, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to the place of business conducted by such person or describe the type of service or class of products sold by such person, by the terms "drugs", "medicine", "drug store", "apothecary", or "pharmacy", unless the place of business so conducted is a pharmacy licensed by the department;

7. Any person to enter into an agreement with a physician, dentist, podiatrist or veterinarian for the compounding or dispensing of secret formula (coded) prescriptions;

8. Any person to sell or distribute any instrument or article, or any recipe, drug or medicine for the prevention of conception to a minor under the age of sixteen years; the sale or distribution of such to a person other than a minor under the age of sixteen years is authorized only by a licensed pharmacist but the advertisement or display of said articles, within or without the premises of such pharmacy is hereby prohibited;

9. Any person to manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device or cosmetic that is adulterated or misbranded;

10. Any person to adulterate or misbrand any drug, device or cosmetic;

11. Any person to receive in commerce any drug, device or cosmetic that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;

12. Any person to sell, deliver for sale, hold for sale, or offer for sale any drug, device or cosmetic in violation of this article;

13. Any person to disseminate any false advertisement;

14. Any person to refuse to permit entry or inspection as authorized by this article;

15. Any person to forge, counterfeit, simulate, or falsely represent, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by rules and regulations promulgated under the provisions of this article;

16. Any person to use for his own advantage, or reveal, other than to the commissioner or his duly authorized representative, or to the court when relevant in any judicial proceedings under this article, any information acquired under authority of this article or concerning any method or process, which is a trade secret;

17. Any person to alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of, or the doing of any other act with respect to a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

18. Any person to use on the labeling of any drug or in any advertising relating to such drug any representation or suggestion that an application with respect to such drug is effective under section sixty-eight hundred seventeen of this chapter or that such is in compliance with the provisions of such section;

19. Any person to violate any of the provisions of section sixty-eight hundred ten of this article;

20. Any person to violate any of the provisions of section sixty-eight hundred sixteen of this article;

21. Any person, to sell at retail or give away in tablet form bichloride of mercury, mercuric chloride or corrosive subli-

mate, unless such bichloride of mercury, mercuric chloride or corrosive sublimate, when so sold, or given away, shall conform to the provisions of national formulary XII. Nothing contained in this paragraph shall be construed to prohibit the sale and dispensing of bichloride or mercury in any form, shape, or color, when combined or compounded with one or more other drugs or excipients, for the purposes of internal medications only, or when sold in bulk in powder form, or to any preparation containing one- tenth of a grain or less of bichloride of mercury;

22. Any pharmacy to fail to properly post the list required by section sixty-eight hundred twenty-six of this article;

23. Any pharmacy to change its current selling price without changing the listed price as provided by section sixty-eight hundred twenty-six of this article;

24. Any person to refuse to permit access to or copying of any record required by this article; or

25. Any manufacturer to sell or offer for sale any drug not manufactured, prepared or compounded under the personal supervision of a chemist or licensed pharmacist or not labeled with the full name of the manufacturer or seller.

§6811-a. Certain drugs to be clearly marked or labeled

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act[1] or by the commissioner of health may be manufactured or commercially distributed within this state in tablet or capsule form unless it has clearly marked or imprinted on each such tablet or capsule in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, number, company name, words, letters, marking or National Drug Code (hereinafter referred to as N.D.C.) number identifying the manufacturer or distributor of the drug; and

(b) an N.D.C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs.

2. No drug for which any prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health contained within a bottle, vial, carton

[1] 21 U.S.C.A. § 301 et seq.

or other container, or in any way affixed or appended to or enclosed within a package of any kind, and designed or intended for delivery in such container or package to an ultimate consumer, shall be manufactured or distributed within this state unless such container or package has clearly and permanently marked or imprinted upon it in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, N.D.C. number, company name, number, letters, words or marking identifying the manufacturer or distributor of the drug;

(b) an N.D.C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs; and

(c) whenever the distributor of the prescription drug product does not also manufacture that product the names and places of business of both shall appear on the label in words clearly distinguishing each.

3. (a) Each manufacturer and distributor shall prepare and submit to the commissioner of health a proposed plan of the manufacturer or distributor, as the case may be, to have its products comply with the marking and labeling requirements of this section.

(b) Such plan shall be in writing and shall give the respective dates by which the various products manufactured or distributed will each contain the required mark or label. The plan shall state the reasons why the projected date of compliance has been proposed and such other information deemed relevant or that the commissioner of health shall require.

(c) The commissioner may either approve the plan as proposed or, after consultation with the manufacturer or distributor, require an amendment or the commissioner may promulgate a plan for the manufacturer or distributor. No plan or amendment to the plan shall be effective until approved or promulgated by the commissioner of health upon a finding by him that the time limitations provided for therein are reasonable and will best carry out the intendment of this section.

4. Each manufacturer and/or distributor shall publish and make available, upon request, to the department of education, to each physician, dentist, pharmacy, hospital or other institution wherein such drugs may be used, a printed material which will identify each imprint used by the manufacturer or distributor. Updated materials shall be provided as changes occur,

upon the filing of an annual request. The provisions of this subdivision shall be deemed to be complied with when a prescription drug product is included in the Physician's Desk Reference.

5. Every person, firm or corporation violating the provisions of this section for any prescription drug product shall be guilty of an offense punishable by a fine of not less than twenty-five hundred dollars nor more than ten thousand dollars. Any prescription drug product prepared or manufactured in violation of this section shall be contraband and subject to seizure either by the state board of pharmacy or by any law enforcement officer of the state.

6. The provisions of this section shall not apply to any tablet or capsule which contains a controlled substance as that term is defined by article thirty-three of the public health law or which is prepared or manufactured by a pharmacist duly licensed by the state which is made by him for the purpose of retail sale from his principal place of business and not intended for resale.

7. The commissioner of health may exempt a particular tablet or capsule from the requirements of this section, upon application by a manufacturer, on the grounds that labeling such a tablet or capsule is unfeasible because of size or texture or other unique characteristics.

8. (a) As used in thie (sic) section, the term "distributor" means the person, firm, corporation or other entity which is not the actual manufacturer of a prescription drug product but which distributes such product for resale under the label of such person, firm corporation or entity.

(b) For purposes of subdivision four "drug product" means the entire supply of the finished dosage form of the drug.

§6811-b. Door-to-door distribution of drugs prohibited

It shall be a violation, punishable by a fine not to exceed two hundred fifty dollars, for a manufacturer, distributor, or seller of drugs or an employee or agent thereof to distribute a free sample of any drug, other than a cosmetic not intended for ingestion, to any residential dwelling unless the sample is given directly to a person who is, or reasonably appears to be, over the age of eighteen. This section shall not be construed to per-

mit distribution where otherwise prohibited by this chapter or any other law.

6812. Special provisions. 1. Where any pharmacy registered by the department is damaged by fire the board shall be notified within a period of forty-eight hours, and the board shall have power to impound all drugs for analysis and condemnation, if found unfit for use. Where a pharmacy is discontinued, the owner of its prescription records shall notify the department as to the disposition of said prescription records, and in no case shall records be sold or given away to a person who does not currently possess a registration to operate a pharmacy.

2. Nothing in this article shall be construed as requiring the prosecution or the institution of injunction proceedings for minor violations of this article whenever the public interest will be adequately served by a suitable written notice of warning.

3. The executive secretary of the state board of pharmacy is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county, or other political subdivision of this state.

§6813. Seizure. 1. Any drug, device or cosmetic that is adulterated, misbranded or may not be sold under the provisions of this chapter, may be seized on petition or complaint of the board and condemned in the supreme court of any county in which it is found. Seizure shall be made:

a. by process pursuant to the petition or complaint, or

b. if the secretary or other officer designated by him has probable cause to believe that the article

(1) is one which may not be sold under the provisions of section sixty-eight hundred seventeen of this chapter, or

(2) is adulterated, or

(3) is so misbranded as to be dangerous to health.

The article shall be seized by order of such officer. The order shall describe the article to be seized, the place where the article is located, and the officer or employee making the seizure. The officer, in lieu of taking actual possession, may affix a tag

or other appropriate marking to the article giving notice that the article has been quarantined and warning all persons not to remove or dispose of it by sale or otherwise until permission for removal or disposal is given by the officer or the court. In case of seizures or quarantine pursuant to such order, the jurisdiction of such court shall attach upon such seizure or quarantine, and a petition or complaint for condemnation shall be filed promptly.

2. The procedure for cases under this section shall conform as much as possible to the procedure for attachment. Any issue of fact joined in any case under this section shall be tried by jury on the demand of either party. The court at any time after seizure and up to the time of trial shall allow by order any party or his agent or attorney to obtain a representative sample of the condemned material, a true copy of the analysis on which the proceeding was based, and the identifying marks or numbers, if any, on the packages from which the samples analyzed were obtained.

3. Any drug, device or cosmetic condemned under this section shall be disposed of by destruction or sale as the court may direct after the decree in accordance with the provisions of this section. The proceeds of the sale, if any, shall be paid into the state treasury after deduction for legal costs and charges. However, the drug, device or cosmetic shall not be sold contrary to the provisions of this article. After entry of the decree, if the owner of the condemned articles pays the costs of the proceedings and posts a sufficient bond as security that the articles will not be disposed of contrary to the provisions of this article, the court may by order direct that the seized articles be delivered to the owner to be destroyed or brought into conformance with this article under supervision of the secretary. The expenses of the supervision shall be borne by the person obtaining the release under bond. Any drug condemned by reason of its being a new drug which may not be sold under this article shall be disposed of by destruction.

4. When the decree of condemnation is entered, court costs and fees, storage and other expense shall be awarded against the person, if any, intervening as claimant of the condemned articles.

5. In any proceeding against the board, or the secretary, or an agent of either, because of seizure, or quarantine, under this

section, the board or the secretary, or such agent shall not be liable if the court finds that there was probable cause for the acts done by them.

§6814. Records of shipment. For the purpose of enforcing provisions of this article, carriers engaged in commerce, and persons receiving drugs, devices or cosmetics in commerce or holding such articles so received, shall, upon the request of an officer duly assigned by the secretary, permit such officer, at reasonable times, to have access to and to copy all records showing the movement in commerce of any drug, device or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof: and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of drug, device or cosmetic to which such request relates: Provided, that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, that carriers shall not be subject to the other provisions of this article by reason of their receipt, carriage, holding or delivery of drugs, devices or cosmetics in the usual course of business as carriers.

§6815. Adulterating, misbranding and substituting. 1. Adulterated drugs. A drug or device shall be deemed to be adulterated:

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations provided in this article.

b. If it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the

standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or, in the absence or inadequacy of such tests or methods of assay, then in accordance with tests or methods of assay prescribed by regulations of the board of pharmacy as promulgated under this article. Deviations from the official assays may be made in the quantities of samples and reagents employed, provided they are in proportion to the quantities stated in the official compendium. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because (1) it exceeds the standard of strength therefor set forth in such compendium, if such difference is plainly stated on its label; or (2) it falls below the standard of strength, quality, or purity therefor set forth in such compendium if such difference is plainly stated on its label, except that this clause shall apply only to such drugs, or classes of drugs, as are specified in regulations which the board shall promulgate when, as applied to any drug, or class of drugs, the prohibition of such difference is not necessary for the protection of the public health. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.

c. If it is not subject to the provisions of paragraph b of this subdivision and its strength differs from or its purity or quality falls below, that which it purports or is represented to possess.

d. If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

e. If it is sold under or by a name not recognized in or according to a formula not given in the United States pharmacopoeia or the national formulary but that is found in some other standard work on pharmacology recognized by the board, and it differs in strength, quality or purity from the strength, quality or purity required, or the formula prescribed in, the standard work.

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph the board may establish reasonable variations as to quantity and exemptions as to small packages.

c. If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the secretary, after investigation, found to be, and by regulations under this article, or by regulations promulgated by the board, designated as, habit forming; unless its label bears the name and quantity, or proportion, of such substance or derivative and in juxtaposition therewith the statement "Warning -- May be habit forming."

e. If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity by percentage or amount of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Pro-

vided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

f. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that, where any requirement of clause (1) of this paragraph, as applied to any drug or device is not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirement.

g. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that, the method of packing may be modified with the consent of the secretary in accordance with regulations promulgated by the board. Wherever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

i. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file

for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

§ 6816. Omitting to label drugs, or labeling them wrongly. 1. (a) Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered or demanded, except where required pursuant to section sixty-eight hundred sixteen-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to section sixty-eight hundred sixteen-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of an apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to the payment of a fine not to exceed one thousand dollars and may be sentenced to imprisonment for a term not to exceed one year. The third con-

viction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the penalty prescribed by law for a misdemeanor, shall forfeit any right which he may possess under the law of this state at the time of such conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding, preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

(b) The provisions of this section shall not apply to the practice of a practitioner who is not the proprietor of a store for the dispensing or retailing of drugs, medicine and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser: provided, however, that the sale of medicines or poisons at wholesale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

(c) The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the generic names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any generic or nonproprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.

§6816-a When substitution is required. 1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber places his signature above the words, "substitute permissible", or in the case of oral prescriptions, the prescriber must expressly state that substitution shall be permitted; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser the laws of that state shall prevail.

§6817. New Drugs. No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug, unless

a. an application with respect thereto has become effective, or in the case of an investigational drug the sponsor has complied with the applicable requirements, under the federal food, drug and cosmetic act, or

b. when not subject to such act, such drug has been tested and has not been found to be unsafe or ineffective for use under the conditions prescribed, recommended or suggested in the labeling thereof, and, prior to selling or offering for sale such drug, there has been filed with the department an application setting forth

(1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;

(2) a full list of the ingredients used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drugs;

(5) such samples of such drug and of the ingredients used as components thereof as the board or secretary may require, and

(6) specimens of the labeling proposed to be used for such drug.

2. An application provided for in paragraph b of subdivision one shall become effective on the one hundred eightieth day after the filing thereof, except that if the secretary or board finds, after due notice to applicant and giving him an opportunity for a hearing, that the drug is not safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall prior to the effective date of the application, issue an order refusing to permit the application to become effective.

3. A drug dispensed on a written or oral prescription of a physician, dentist, podiatrist or veterinarian (except a controlled substance), shall be exempt from the requirements of this section if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription and the name of the physician, dentist, podiatrist or veterinarian issuing the prescription and the name of the patient. In addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

4. The board shall promulgate regulations for exempting from the operation of this section drugs (and with the concurrence of the commissioner of health, pursuant to article thirty-three of the public health law, controlled substances) intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs and labeled "For Investigational Use Only." Such regulations may, within the discretion of the board, among other conditions relating to the protection of the public health, provide for conditioning such exemptions upon:

a. The submission to the secretary before any clinical testing of a new drug is undertaken of reports by the manufacturer or sponsor of the investigation of such drug, of preclinical tests, including tests on animals of such drug adequate to justify the proposed clinical testing.

b. The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator or to clinics for administration to human beings; and

c. The establishment and maintenance of such records and the making of such reports to the board by the manufacturer or the sponsor of the investigation of such drugs of data including, but not limited to, analytical reports by investigators obtained as the result of such investigational use of such drug as the board finds will enable it to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subdivision one of this section.

5. This section shall not apply to any drug which was licensed under the federal virus, serum, and toxin act of July first, nineteen hundred two (32 Stat. 728) or is licensed under section two hundred sixty-two of the public health service act of July first, nineteen hundred forty-four (58 Stat. 682), or under the federal virus, serums, toxins, antitoxins and analogous products act of March fourth, nineteen hundred thirteen (37 Stat. 832).

§6818. **Adulterated and misbranded cosmetics.** 1. A cosmetic shall be deemed to be adulterated:

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon "Caution--this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made.

This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph e the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

b. If it consists in whole or in part of any filthy, putrid, or decomposed substance.

c. If it has been prepared, packaged, packed, shipped or held in any insanitary condition or in any other condition whereby it may have been rendered injurious to health.

d. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

e. If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by this article.

2. A cosmetic shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations.

c. If any word, statement, or other information required by or under authority of this article to appear on the label is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. (1) If its container is so made, formed, or filled as to be misleading; or (2) if it bears a copy, counterfeit, or colorable imitation of a trademark, label, or identifying name or design of another cosmetic.

§6819. **Regulations making exceptions.** The board shall promulgate regulations exempting from any labeling requirement of this article drugs, devices and cosmetics which are, in accordance with the practice of the trade, to be processed, la-

beled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs, devices and cosmetics are not adulterated or misbranded under the provisions of this article upon removal from such processing, labeling, or repacking establishment.

§6820. Certification of coal-tar colors for drugs and cosmetics. The board shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

§6821. Poison schedules; register. 1. The following schedules shall remain in force until revised by the board and approved by the department.

Schedule A. Arsenic, atropine, corrosive sublimate, potassium cyanide, chloral hydrate, hydrocyanic acid, strychnine and all other poisonous vegetable alkaloids and their salts and oil of bitter almond containing hydrocyanic acid.

Schedule B. Aconite, belladonna, cantharides, colchicum, conium, cotton root, digitalis, ergot, hellebore, henbane, phytolacca, strophanthus, oil of savin, oil of tansy, veratrum viride and their pharmaceutical preparations, arsenical solutions, carbolic acid, chloroform, creosote, croton oil, white precipitate, methyl or wood alcohol, mineral acids, oxalic acid, paris green, salts of lead, salts of zinc, or any drug, chemical or preparation which is liable to be destructive to adult human life in quantities of sixty grains or less.

2. It shall be unlawful for any person to sell at retail or to furnish any of the poisons of schedules A and B without affixing or causing to be affixed to the bottle, box, vessel or package, a label with the name of the article and the word "poison" distinctly shown and with the name and place of business of the seller all printed in red ink together with the name of such poisons printed or written thereupon in plain, legible characters.

3. Manufacturers and wholesale dealers in drugs, medicines, pharmaceutical preparations, chemicals or poisons shall affix or cause to be affixed to every bottle, box, parcel or outer

inclosure of any original package containing any of the articles of schedule A a suitable label or brand in red ink with the word "poison" upon it.

4. Every person who disposes of or sells at retail or furnishes any poisons included in schedule A shall before delivering the same enter in a book kept for that purpose the date of sale, the name and address of the purchaser, the name and the quantity of the poison, the purpose for which it is purchased and the name of the dispenser. The poison register must be always open for inspection by the proper authorities and must be preserved for at least five years after the last entry. Such person shall not deliver any of the poisons of schedule A or schedule B until he has satisfied himself that the purchaser is aware of its poisonous character and that the poison is to be used for a legitimate purpose. The provisions of this paragraph do not apply to the dispensing of drugs or poisons on a doctor's prescription.

5. The board may add to or may delete from any of the schedules from time to time as such action becomes necessary for the protection of the public.

§6822. Examinations and investigations. The secretary is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county or other political subdivision of this state, duly commissioned by the secretary as an officer of the board.

§6823. Factory inspection. For purposes of enforcement of this article, officers duly designated by the secretary are authorized:

(1) to enter, at reasonable times, any factory, warehouse or establishment in which drugs, devices or cosmetics are manufactured, processed, packed, or held, for introduction into commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such drugs, devices or cosmetics in commerce; and

(2) to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

§6824. Injunction proceedings. In addition to the remedies hereinafter provided, the secretary is hereby authorized to apply to the court of the proper venue for an injunction to restrain any person from (a) introducing or causing to be introduced into commerce any adulterated or misbranded drug, device or cosmetic; or (b) from introducing or causing to be introduced in commerce any new drug which does not comply with the provisions of this article; or (c) from disseminating or causing to be disseminated a false advertisement, without being compelled to allege or prove that an adequate remedy at law does not exist.

§6825. Proof required in prosecution for certain violations. 1. In an action or proceeding, civil or criminal, against a person for violating such provisions of this article which relate to the possession of, compounding, retailing or dispensing of misbranded, substituted or imitated drugs, poisons or cosmetics, when it shall be necessary that an analysis be made for the purpose of establishing the quality of such drug, poison or cosmetic so as to determine the fact of misbranding, substituting or imitating, then it shall be required to prove at the trial or hearing of such action or proceeding, that the person, taking the same for analysis separated it into two representative parts, hermetically or otherwise effectively and completely sealed, delivered one such sealed part to the seller, manufacturer, wholesaler, pharmacist, druggist or storekeeper from whose premises such sample was taken and delivered the other part so sealed to the chemist designated by the state board of pharmacy; and the facts herein required to be proven shall be alleged in the complaint or information by which such action or proceeding was begun. The rules of the board shall be proven prima facie by the certificate of the secretary.

2. Any person accused of violation of any of the provisions of this article relating to adulterating, misbranding, substitution or imitation shall not be prosecuted or convicted or suffer any of the penalties, fines or forfeitures for such violation, if he establishes upon the hearing or trial that the drug, device or cosmetic alleged to be adulterated, misbranded, substituted or imitated was purchased by him under a written guaranty of the manufacturer or seller to the effect that said drug, device or cosmetic was not adulterated or misbranded, within the mean-

ing of this article and proves that he has not adulterated, misbranded, substituted or imitated the same, provided the seller has taken due precaution to maintain the standard set for the drug, device or cosmetic. A guaranty, in order to be a defense to a prosecution or to prevent conviction or to afford protection, must state that the drug, device or cosmetic to which it refers is not adulterated, misbranded, substituted or imitated within the meaning of the provisions of this article and must state also the full name and place of business of the manufacturer, wholesaler, jobber or other person from whom the drug, device or cosmetic was purchased, and the date of purchase. The act, omission or failure of any officer, agent or other employee acting for or employed by any person within the scope of his authority or employment shall in every case be the act, omission or failure of such person as well as that of the officer, agent or other employee, and such person shall be equally liable for violations of this article by a partnership, association or corporation, and every member of the partnership or association and the directors and general officers of the corporation and the general manager of the partnership, association or corporation shall be individually liable and any action, prosecution or proceeding authorized by this article may be brought against any or all of such persons. When any prosecution under this article is made on the complaint of the board, any fines collected shall be paid into the state treasury as provided by this article.

3. No publisher, radio-broadcast licensee, advertising agency, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates, shall be subject to the penalties provided by this article by reason of the dissemination by him of any false advertisement, unless he has refused, on the request of the secretary, to furnish the secretary the name and post-office address of the manufacturer, packer, distributor, seller or advertising agency, who caused him to disseminate such advertisement.

§6826. **Posting.** 1. Every pharmacy shall post a list of drugs together with their current selling price in the manner prescribed by this section.

2. a. Such list shall be prepared from time to time by the board and distributed to each pharmacy in the state. The list shall be a compendium of the one hundred fifty most frequently prescribed drugs together with their usual dosages for which a prescription is required by the provisions of the "Federal Food, Drug and Cosmetic Act" (21 U.S.C. 301, et seq.; 52 Stat. 1040, et seq.), as amended, or by the commissioner of health.

b. Such list shall contain a notice in block letters not less than one inch in height which shall read: "Consult your pharmacist for the selection of the most economical drug product available to fill your doctor's prescription."

3. The board shall provide appropriate space on the list for inclusion by a pharmacy of its current selling price for each listed drug and dosage. The current selling price means the actual price to be paid by a retail purchaser to the pharmacy for any listed drug at the listed dosage.

4. The list shall be conspicuously posted at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing.

5. Nothing contained herein shall prevent a pharmacy from changing the current selling price at any time, provided that the listed price is simultaneously adjusted to reflect the new current selling price.

§ 110. Refunds.

(2) Applicants for professional licenses not receiving such licenses may be granted partial refunds not exceeding fifty percent of the fee paid to the department unless they have failed the examinations for such licenses, in which case such applicants may not receive a refund. Each applicant for a professional license who has at any time received a partial refund of an initial license application fee shall pay all required fees upon submitting any subsequent application for initial licensure.

RULES OF THE BOARD OF REGENTS

PART 3

THE UNIVERSITY OF THE STATE OF NEW YORK
STATE EDUCATION DEPARTMENT

§ 3.3 Board of Regents disciplinary procedures. The following rules shall apply to disciplinary matters determined pursuant to the provisions of Title VIII of the Education Law:

(a) The respondent shall be given at least twenty (20) days' notice of the time and place of the meeting of the Regents review committee.

(b) The respondent shall have 12 days to file an original and 10 copies of a brief with the executive director of the Office of Professional Discipline. The State Education Department or the Department of Health may submit an answering brief, with a copy to respondent, at least one day prior to the scheduled date for review.

(c) The time to be allotted to counsel for presentation of their arguments shall be determined by the Regents review committee.

(d) After the meeting of the Regents review committee, it shall transmit a written report of its review to the Board of Regents. The report shall be signed by the chairperson or by a majority of the members of the Regents review committee which reviewed the matter.

(e) The Commissioner of Education shall execute all orders in connection with disciplinary proceedings, as directed by the Board of Regents. An order shall be effective as of the date of the personal service of the order upon the respondent or five days after mailing by certified mail to the last known address.

(f) An application for reconsideration of a determination of the Board of Regents in disciplinary proceedings may be made, in writing, at any time subsequent to the service of the order of the Commissioner of Education in accordance with such determination. The making of such an application shall not effect a stay of the determination sought to be reconsidered. No such application will be granted in the absence of a showing that the determination was based on an error of law, or that there is new and material evidence which was not previously avail-

able, or that circumstances have occurred subsequent to the original determination which warrant a reconsideration of the measure of discipline. The original and nine copies of each such application and all supporting papers shall be submitted to the executive director of the Office of Professional Discipline, who, in the exercise of discretion, shall determine whether the application warrants referral to the Board of Regents for its determination based upon any of the grounds set forth by the applicant as the basis for the application. If such referral is warranted, the executive director shall deliver one copy to the attorney assigned to the case, and shall refer the application to a Regents review committee or, if the determination of the Board of Regents was made pursuant to the provisions of article II-A of the Public Health Law to the Commissioner of Health. The Commissioner of Health may submit a recommendation to the Regents review committee. Oral argument on applications submitted to a Regents review committee will not be permitted, unless requested by such committee, but the respondent may submit affidavits and a brief, and the State Education Department or the Department of Health may submit answering affidavits and a brief within 20 days after receipt of the application. The Regents review committee shall submit a written report of its recommendation to the Board of Regents, which shall make the final determination on all such applications.

PART 17

DISCIPLINARY PROCEEDINGS IN THE PROFESSIONS

§ 17.1 Complaints or other information. All complaints or other information relating to licensees authorized to practice a profession under Title VIII of the Education Law shall be referred to the executive director of the Office of Professional Discipline.

§ 17.2 Investigation. The executive director of the Office of Professional Discipline or that officer's designee shall, in matters involving possible professional misconduct, initiate an investigation of each such complaint or other information.

§ 17.3 Prosecution or settlement of disciplinary proceedings. Prosecution or settlement of disciplinary proceedings shall be conducted as provided in Title VIII of the Education Law, and as provided in this Part.

§ 17.4 Reports. The executive director of the Office of Professional Discipline or that officer's designee shall submit a report by April 1st of each year on the status of cases investigated during the previous year, as well as on the disposition of any criminal or civil matters processed through the office, to the chairperson of the State Board for each of the professions supervised by the Board of Regents.

§ 17.5 Consent orders. Disciplinary proceedings conducted pursuant to the provisions of Title VIII of the Education Law may be disposed of in accordance with the following procedure:

(a) A licensee who is under investigation, or against whom charges have been voted, who admits guilt to at least one of the acts of misconduct alleged or charged, in full satisfaction of all allegations or charges, or who does not contest the allegations or charges or who cannot successfully defend against at least one of the acts of misconduct alleged or charged, shall notify the executive director of the Office of Professional Discipline or the director's designee.

(b) If the executive director of the Office of Professional Discipline or the director's designee, a designated member of the State Board for the applicable profession, and the licensee agree to a statement by the licensee admitting guilt to one or more of the allegations or charges or setting forth a decision not to contest the allegations or charges or stating that the licensee cannot successfully defend against such allegations or charges and agreeing to a proposed penalty, and if a designated member of the Board of Regents thereafter agrees to such statement and proposed penalty, a written application, signed by all the above, shall be submitted by the licensee to the Board of Regents based upon the statement and proposed penalty consenting to the issuance of an order of the Commissioner of Education effectuating such penalty. The provisions of this section shall also apply to licensees and registrants subject to section 230 of the Public Health Law and to article 137 of the Education Law. With respect to licensees subject to section 230 of the Public Health Law, the agreement of the director of the Office of Professional Medical Conduct or that officer's designee, and of the Commissioner of Health or his or her designee, to the statement and proposed penalty and their signatures on the application shall be required in lieu of the agreement and signature of the executive director, Office of Professional Discipline. With respect to licensees subject to the provisions of section 230 of the Public Health Law, the term *State Board* as used in this section means the State Board for Professional Medical Conduct. With respect to licensees and registrants subject to article 137 of the Education Law, the agreement of the executive secretary of the State Board of Pharmacy to the statement and proposed penalty and his or her signature on the application shall also be required.

(c) The application shall be in such form and shall contain such substance as is acceptable to the executive director of the Office of Professional Discipline or the director's designee.

(d) In the event an application is not granted by the Board of Regents, nothing contained therein shall be binding upon the licensee or construed to be an admission of any act of misconduct alleged or charged, and such application shall not be used against the licensee in any way. Any such application shall be kept in strict confidence during the pendency of the disciplinary proceeding. In addition, such denial by the Board of

Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(e) In the event the Board of Regents grants the application, the Commissioner of Education shall issue an order in accordance therewith.

§ 17.6 Surrender of license. Disciplinary proceedings conducted pursuant to the provisions of Title VIII of the Education Law may be disposed of in accordance with the following procedure:

(a) A licensee who is under investigation or against whom charges have been voted, who wishes to surrender his or her license to practice any of the professions enumerated in Title VIII, shall notify the executive director of the Office of Professional Discipline or that officer's designee.

(b) An application to surrender a license shall be based upon a statement that the licensee admits guilt to at least one of the acts of misconduct alleged or charged, in full satisfaction of all allegations or charges, or does not contest the allegations or charges, or cannot successfully defend against at least one of the acts of misconduct alleged or charged. If the executive director or the director designee, a designated member of the State Board for the applicable profession, and the licensee agree to such statement, and if a designated member of the Board of Regents thereafter agrees to such statement, a written application, signed by the licensee, shall be submitted to the Board of Regents. The application shall be in such form and shall contain such substance as is acceptable to the executive director of the Office of Professional Discipline or the director's designee. The provisions of this section shall also apply to licensees and registrants subject to section 230 of the Public Health Law and to article 137 of the Education Law. With respect to licensees subject to section 230 of the Public Health Law, the agreement of the director of the Office of Professional Medical Conduct or that officer's designee and the Commissioner of Health or his or her designee to the statement, and their signature on the application shall be required in lieu of the agreement and signature of the executive director of the Office of Professional Discipline. With respect to li-

censees subject to the provisions of section 230 of the Public Health Law, the term *State Board* as used in this section means the State Board for Professional Medical Conduct. With respect to licensees and registrants subject to article 137 of the Education Law, the agreement of the executive secretary of the State Board of Pharmacy to the statement and his or her signature on the application shall also be required.

(c) In the event the application is not granted by the Board of Regents, nothing contained therein shall be binding upon the licensee or construed to be an admission of any act of misconduct alleged or charged and such application shall not be used against the licensee in any way. The application shall be kept in strict confidence during the pendency of the disciplinary proceeding. In addition, any such denial by the Board of Regents shall be made without prejudice to the continuance of any disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(d) In the event the Board of Regents grants the application, the Commissioner of Education shall issue an order in accordance therewith. The order shall include a provision that the licensee may not apply for the restoration of the license affected by the granted application until at least one year has elapsed from the date of the service of such order.

§ 17.7 Violation of probation.

(a) Upon the receipt of information indicating that the respondent may be in violation of any of the terms or conditions of respondent's probation, the Department shall conduct an investigation.

(b) The executive director of the Office of Professional Discipline shall review the results of the investigation and if the executive director determines that a violation of probation proceeding is warranted, shall give notice to the respondent, by letter, of the facts forming the basis of the alleged violation of respondent's probation. The respondent, in said letter, shall be requested to indicate whether there is any dispute as to the facts, and shall be entitled to a hearing thereon.

(c) If the respondent does not dispute the facts forming the basis of the alleged violation of probation, the matter shall be submitted to the Regents Review Committee for its review and

recommendation(s) as to whether, based upon the undisputed facts, there has been a violation of the terms or conditions of respondent's probation and, if so, as to the measure of discipline to be imposed upon the respondent.

(d) If the respondent disputes any of the facts forming the basis of the alleged violation of probation, the respondent shall be afforded a hearing before a hearing officer appointed by the commissioner to hear and make findings of fact, conclusions of law, and recommendation(s). The department shall give the respondent at least 10 days' notice of the hearing, 15 if by mail. The evidence in support of the application shall be presented by counsel on behalf of the department and the respondent shall also have the right to be represented by counsel. The department and the respondent have the right to produce witnesses and other evidence, to cross-examine witnesses, and to examine any other evidence produced at the hearing. A stenographic record of the hearing will be made and the hearing officer shall not be bound by the rules of evidence, but the findings of fact and conclusions of law of the hearing officer shall be based upon substantial evidence.

(e) The report of the hearing officer shall be reviewed by the Regents Review Committee.

(f) The Regents Review Committee shall notify the respondent, at least seven days before its meeting, of the time and place of such meeting, and shall also notify the respondent of the opportunity of the respondent to appear in person and to be represented by counsel at such meeting.

(g) The Regents Review Committee shall transmit the report of the hearing officer and a written report of its review to the Board of Regents. The final determination shall be made by the Board of Regents and the commissioner shall issue an order implementing such determination.

(h) The measure of discipline to be imposed for any violation of probation may be to continue the respondent on probation for a period in addition to the period of probation imposed in the original order, or to terminate the probation, vacate the stay of execution, and impose any measure of discipline authorized by section 6511 of the Education Law. A violation of probation shall constitute unprofessional conduct, and may constitute the basis for proceedings under either the provisions of sections 6510 of the Education Law or of this Part.

§ 17.8 **Hearing panel; administrative officers.** Findings of fact, recommendations as to penalties to be imposed, and any other actions taken by a hearing panel in disciplinary proceedings, except as hereinafter set forth, shall be made by majority vote. Any determination of guilt shall require a minimum of a four fifths vote of the hearing panel. An administrative officer, admitted to practice as an attorney in the State of New York, shall rule on all motions, procedures and other legal objections, and draft a report which shall reflect the determination and recommendation of the panel and be subject to the approval of and signature by the panel chairperson on behalf of the panel. The administrative officer shall not be entitled to vote.

§ 17.9 Summary suspensions.

(a) If the executive director of the Office of Professional Discipline or that officer's designee believes that the public health, safety and welfare imperatively requires emergency action against a professional license, certificate, registration, permit or other authorization of the licensee to practice under Title VIII of the Education Law, the executive director or the director's designee may make an application, on behalf of the department, to the Board of Regents for the summary suspension of said authorization pending the prompt institution prosecution and completion of formal disciplinary proceedings as provided under section 6510 of the Education Law.

(b) Summary suspension proceedings shall be commenced by the service on the licensee of a notice of hearing and a verified petition. The notice of hearing shall state the time and place of oral argument on the application for summary suspension and the regent designated by the chancellor to hear the matter, and shall include a copy of this rule. The notice of hearing and petition shall be personally served upon the licensee no later than five days prior to the date set for oral argument. If personal service cannot be made after due diligence, the notice of hearing and petition may be served by certified mail, to the licensee's last known address, not less than eight days prior to the date set for oral argument. The petition shall set forth the basis for the application and shall include sworn statements upon personal knowledge and/or exhibits demonstrating probable cause to believe that respondent has committed professional misconduct and that the public health,

safety or welfare imperatively requires emergency action to summarily suspend respondent's license. A verified answer and any sworn statements and supporting exhibits may be served by respondent upon the executive director of the Office of Professional Discipline or that officer's designee no later than two days prior to the date set for oral argument. The executive director or designee may serve a verified reply, together with any sworn statement and supporting exhibits, to the answer no later than the day prior to the date set for oral argument. The answer and/or reply may be served by certified mail by mailing to the addressee no later than three and two days, respectively, prior to the date set for oral argument. The petition, answer and reply, together with any sworn statement and supporting exhibits, shall be transmitted at the time of service of each paper to the regent designated to hear the case. Saturdays, Sundays and legal holidays shall be excluded in calculating the periods of time set forth in this subdivision.

(c) At the oral argument, the Office of Professional Discipline and respondent and/or his or her attorney shall have the right to be heard, but no testimony shall be taken and no transcript of oral arguments shall be required. No further papers shall be submitted at the oral argument except by permission of the regent designated to conduct the proceeding.

(d) The regent designated by the chancellor to conduct the proceeding shall submit a written report of his or her conclusions and recommendation(s) to the Board of Regents, which shall determine whether to grant or deny the application for summary suspension. A determination by the Board of Regents granting the application must be based upon a finding that the public health, safety or welfare imperatively requires emergency action.

(e) Any determination of the Board of Regents shall be without prejudice to the department or licensee in any subsequent formal disciplinary proceeding.

PART 28

DETERMINATION OF GOOD MORAL CHARACTER IN THE PROFESSIONS

§28.1 Determination of good moral character. The determination of whether an applicant for authorization to practice a profession under Title VIII of the Education Law is of good moral character shall be made in accordance with the procedures specified in this Part.

§28.2 Information. All information indicating that an applicant has been convicted of a crime, or has committed an act which raises a reasonable question as to the applicant's moral character, shall be referred to the executive director of the Office of Professional Discipline or his or her designee.

§28.3 Investigation. The executive director of the Office of Professional Discipline or his or her designee shall arrange for a full and complete investigation of the circumstances surrounding such conviction or act. If it is determined that a reasonable question exists as to the applicant's moral character, then the executive director, or his or her designee, shall submit the results of the investigation, including any letters of reference from peers or others which may have been submitted by the applicant, to a panel of the appropriate professional State Board for its review. The panel shall consist of three or more members of the State Board.

§28.4 Review. Upon such review, the panel, by majority vote, may conclude in favor of the applicant to the effect that the moral character of the applicant is adequate for licensure, thereby fulfilling that licensure requirement, and the applicant and the director of the Division of Professional Licensing Services shall be notified of such conclusion by the Office of Professional Discipline. If, upon such review, the panel concludes, by a majority vote, that a substantial question exists as to the moral character of the applicant, the applicant shall be notified thereof. Upon the written request of the applicant, within 30 days after receipt of such notice, the department shall schedule a hearing on such question.

§28.5 Hearing. The applicant shall be given 15 days' notice, by mail, of the time and place of the hearing and a statement of the matters asserted which raised the question of the applicant's moral character. The applicant may be represented at the hearing by an attorney, may cross-examine witnesses, may produce witnesses, and may present evidence in support of the applicant's good moral character. The hearing, at which a verbatim record shall be taken, shall take place before a panel consisting of three or more members of the appropriate professional State Board, and before an administrative officer admitted to practice as an attorney in the State of New York, designated by the department. Such administrative officer shall have authority to rule on all motions, procedures and other legal objections, but shall not be entitled to vote in the determination of the panel. The determination of the panel shall be made by a majority vote of the panel and shall be rendered in a written report which shall be drafted by the administrative officer, shall reflect the determination and recommendations of the panel, and shall be subject to the approval of and signature by the panel chairperson on behalf of the panel. Copies of the report shall be forwarded to the director of the Division of Professional Licensing Services and to the applicant.

§28.6 Appeal. The applicant or the executive director of the Office of Professional Discipline may appeal the determination of the panel concerning the licensure requirement of good moral character by filing a written notice of appeal therefrom with the Committee on the Professions within 30 days after service of the report of the panel upon the party taking the appeal. In the event no appeal is taken from the determination of the panel, the determination of the panel shall be final. In the event either party appeals from the determination of the panel, the appellant may submit a brief to the Committee on the Professions and the opposing party within 30 days after filing the notice of appeal. An answering brief may be filed by the opposing party with the Committee on the Professions within 20 days after the receipt by the opposing party of the brief submitted by the appellant. The Committee on the Professions may affirm, reverse or modify the determination of the panel and/or make such other determination as it may deem just and proper under the circumstances. The determination of the

Committee of the Professions shall be final and copies thereof shall be forwarded to the applicant and to the executive director of the Office of Professional Discipline.

§28.7 **Reapplication.** Whether or not the applicant appeals from the determination of the panel, the applicant may reapply for licensure to the director of the Division of Professional Licensing Services after the expiration of 18 months from the date of the service of the report of the panel.

PART 29

UNPROFESSIONAL CONDUCT

§29.1 General provisions for all professions.

(a) Unprofessional conduct shall be the conduct prohibited by this section. The provisions of these rules applicable to a particular profession may define additional acts or omissions as unprofessional conduct and may establish exceptions to these general prohibitions.

(b) Unprofessional conduct in the practice of any profession licensed or certified pursuant to Title VIII of the Education Law shall include:

(1) willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession;

(2) exercising undue influence on the patient or client, including the promotion of the sale of services, goods, appliances or drugs in such manner as to exploit the patient or client for the financial gain of the practitioner or of a third party;

(3) directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services;

(4) permitting any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice the same profession, or a legally authorized trainee practicing under the supervision of a licensed practitioner. This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a professional licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice, except as otherwise provided by law with respect to a facility licensed pursuant to article 28 of the Public Health Law or article 13 of the Mental Hygiene Law;

(5) conduct in the practice of a profession which evidences moral unfitness to practice the profession;

(6) willfully making or filing a false report, or failing to file a report required by law or by the Education Department, or willfully impeding or obstructing such filing, or inducing another person to do so;

(7) failing to make available to a patient or client, upon request, copies of documents in the possession or under the control of the licensee which have been prepared for and paid for by the patient or client;

(8) revealing of personally identifiable facts, data or information obtained in a professional capacity without the prior consent of the patient or client, except as authorized or required by law;

(9) practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform, or performing without adequate supervision professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person's life or health is in danger;

(10) delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, by experience or by licensure, to perform them;

(11) performing professional services which have not been duly authorized by the patient or client or his or her legal representative;

(12) advertising or soliciting for patronage that is not in the public interest:

(i) advertising or soliciting not in the public interest shall include but not be limited to advertising or soliciting that:

(a) is false, fraudulent, deceptive, misleading, sensational or flamboyant;

(b) represents intimidation or undue pressure;

(c) uses testimonials;

(d) guarantees any service;

(e) makes any claim relating to professional services or products or the cost or price therefor which cannot be

substantiated by the licensee, who shall have the burden of proof;

(f) makes claims of professional superiority which cannot be substantiated by the licensee, who shall have the burden of proof; or

(g) offers bonuses or inducements in any form other than a discount or reduction in an established fee or price for a professional service or product.

(ii) the following shall be deemed appropriate means of informing the public of the availability of professional services:

(a) informational advertising not contrary to the foregoing prohibitions; and

(b) the advertising in a newspaper, periodical or professional directory or on radio or television of fixed prices, or a stated range of prices, for specified routine professional services, provided that if there is an additional charge for related services which are an integral part of the overall service being provided by the licensee, the advertisement shall so state, and provided further that the advertisement indicates the period of time for which the advertised prices shall be in effect;

(iii)(a) all licensees placing advertisements shall maintain, or cause to be maintained, an exact copy of each advertisement, transcript, or videotape thereof as appropriate for the medium used, for a period of one year after its last appearance. This copy shall be made available for inspection upon demand of the Education Department or in the case of physicians, physician's and specialist's assistants, the Department of Health;

A licensee shall not compensate or give anything of value to representatives of the press, radio, television or other communications media in anticipation of or in return for professional publicity in a news item;

(iv) No demonstrations, dramatizations or other portrayals of professional practice shall be permitted in advertising on radio or television;

(13) failing to respond within 30 days to written communications from the Education Department or the Department of Health and to make available any relevant records with respect to an inquiry or complaint about the licensee's unpro-

fessional conduct. The period of 30 days shall commence on the date when such communication was delivered personally to the licensee. If the communication is sent from either department by registered or certified mail, with return receipt requested, to the address appearing in the last registration the period of 30 days shall commence on the date of delivery to the licensee, as indicated by the return receipt;

(14) violating any term of probation or condition or limitation imposed on the licensee by the Board of Regents pursuant to Education Law section 6511.

§ 29.2 General provisions for health professions.

(a) Unprofessional conduct shall also include, in the professions of:

medicine	ophthalmic dispensing
acupuncture	psychology
physical therapy	social work
physician's assistant	massage
specialist's assistant	occupational therapy
chiropractic	speech pathology
dentistry	audiology
dental hygiene	nursing (registered professional nurse, licensed practical nurse)
pharmacy	
podiatry	
optometry	

(1) abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital, clinic or other health care facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients;

(2) willfully harassing, abusing or intimidating a patient either physically or verbally;

(3) failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient. Unless otherwise provided by law, all patient records must be retained for at least six years. Obstetrical records

and records of minor patients must be retained for at least six years, and until one year after the minor patient reaches the age of 21 years;

(4) using the word "Doctor" in offering to perform professional services without also indicating the profession in which the licensee holds a doctorate;

(5) failing to exercise appropriate supervision over persons who are authorized to practice only under the supervision of the licensed professional;

(6) upon a patient's written request, failing to make available to a patient, or, to another licensed health practitioner consistent with that practitioner's authorized scope of practice, copies of the record required by paragraph (3) of this subdivision and copies of reports, test records, evaluations or X-rays relating to the patient which are in possession or under the control of the licensee, or failing to complete forms or reports required for the reimbursement of a patient by a third party. Reasonable fees may be charged for such copies, forms or reports, but prior payment for the professional services to which such records relate may not be required as a condition for making such reports available. A practitioner may, however, withhold information from a patient if, in the reasonable exercise of his or her professional judgment, he or she believes release of such information would adversely affect the patient's health, and this section shall not require release, to the parent or guardian of a minor, of records or information relating to venereal disease or abortion except with the minor's consent. This provision shall apply in lieu of section 29.1(b)(7) of this Part;

(7) guaranteeing that satisfaction or a cure will result from the performance of professional services;

(8) ordering of excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient;

(9) claiming or using any secret or special method of treatment which the licensee refuses to divulge to the State Board for the profession;

(10) failing to wear an identifying badge, which shall be conspicuously displayed and legible, indicating the practitioner's name and professional title authorized pursuant to the Education Law, while practicing as an employee or operator of a hospital, clinic, group practice or multiprofes-

sional facility, or at a commercial establishment offering health services to the public;

(11) entering into an arrangement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions;

(12) with respect to all professional practices conducted under an assumed name, other than facilities licensed pursuant to article 28 of the Public Health Law or article 13 of the Mental Hygiene Law, failing to post conspicuously at the site of such practice the names and licensure field of all of the principal professional licensees engaged in practice at that site (i.e., principal partners, officers or principal shareholders).

§29.7 Special provisions for the profession of pharmacy.

(a) Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

(1) dispensing a written prescription which does not bear the name, address and age of the patient for whom it is intended; the date on which it was written; the name, strength, if applicable, and the quantity of the drug prescribed; directions for use, if applicable; and, the name, address, telephone number, profession and signature of the prescriber; provided that the pharmacist may write on the prescription the address and age of the patient, the strength and quantity of the drug prescribed, the directions for use and the prescriber's address, telephone number and profession if these are missing or unclear. If the address and age of the patient and the address, telephone number and profession of the prescriber are missing from the prescription, the pharmacist shall not be required to enter any of these items on the prescription if the information is otherwise readily available in the records of the pharmacy. An order for a drug to be dispensed for an inpatient in a health care facility by the pharmacy of that facility may be transmitted to the pharmacy in accordance with written procedures approved by the medical or other authorized board of the facility. The items of information required by this paragraph which are found in the records reg-

ularly maintained by the facility and which are not essential to the execution of the order need not appear on the order which is transmitted to the pharmacy. A drug which is dispensed for an inpatient in a health care facility by the pharmacy of that facility may be labeled in accordance with the policy adopted by the medical or other authorized board of the facility. That policy shall insure that all the information required by law to be placed on prescription labels is readily available to all concerned parties and that accuracy and safety prevail in the dispensing process. Prescriptions written for controlled substances shall meet the requirements of Article 33 of the Public Health Law. The address of a patient in a hospital or other health care facility may, for the purpose of a prescription, be that of the facility. An order for a drug for a particular patient issued by a practitioner authorized to prescribe, and transmitted to a pharmacy for dispensing, shall constitute a prescription;

(2) failure by a pharmacist to reduce to writing a prescription transmitted orally which writing shall include all the information required by paragraph (1) of this subdivision and the signature or readily identifiable initials of the receiver of the oral prescription, provided that oral prescriptions for controlled substances shall meet the requirements of Article 33 of the Public Health Law;

(3) failure by a pharmacist dispensing a prescription to enter on the prescription the date of dispensing and to sign or initial legibly the prescription in such a manner as not to interfere with any other information on the prescription; provided that when the prescription is dispensed by an intern, the prescription shall bear the signature or readily identifiable initials of the intern and of the pharmacist who is supervising the intern;

(4) refilling a prescription without entering on the reverse of the prescription the date of the refill and the signature or readily identifiable initials of the pharmacist and of the intern, if applicable, dispensing the refill, except as provided in paragraph (8) of this subdivision. As a refill instruction, the pharmacist may accept a number of times, a time period, such as one year, or the Latin phrase "pro re nata" (abbreviated prn-meaning "as needed"). In the case of the latter, the pharmacist shall refill the prescription once only.

The pharmacist receiving an oral order to refill a prescription shall reduce the order to writing and shall sign or initial it legibly as the recipient of the oral order. When a prescription is refilled, the date placed on the label shall be the date of the refill;

(5) using or substituting without authorization one or more drugs in the place of the drug or drugs specified in a prescription. Unauthorized use or substitution occurs if the same is done without the knowledge and consent of the prescriber. If other than the ingredients specified are utilized by the pharmacist in compounding or dispensing the prescription, improper substitution shall be presumed unless there shall be entered upon the reverse of the original prescription information setting forth the facts of the substitution, the date, time and manner in which authorization for substitution was given and the signature of the pharmacist who received such authorization;

(6) failure to identify a generic product dispensed on a prescription by writing the name of the manufacturer and of the distributor, if different, on the prescription and on the label, except as otherwise provided in Education Law section 6816-a (1) (c);

(7) failure to number prescriptions consecutively and file them in a numerical or other form which provides for ready retrieval of the prescriptions; provided that orders for drugs to be dispensed for inpatients in a health care facility, including but not limited to a general hospital, in the pharmacy of that facility under a drug distribution system approved by the medical or other authorized board of the facility, need not be numbered if the orders are otherwise readily available and retrievable; and, provided further that prescriptions for controlled substances shall be filed in accordance with the provisions of Article 33 of the Public Health Law;

(8) failure to maintain in a form which provides for ready retrieval of prescriptions a daily record of all prescriptions filled and refilled which identifies clearly the practitioner who ordered the prescription, the patient for whom the prescription is intended, the signature or readily identifiable initials of the pharmacist who filled or refilled the prescription, and the number assigned to the prescription where ap-

plicable. The record of the dispensing of a drug for an inpatient in a health care facility, including but not limited to a general hospital, by the pharmacy of that facility may be maintained in a form which is consistent with the record of the total health service provided to the patient provided the information required by this paragraph is readily retrievable and available. Original prescriptions filed in accordance with the provisions of paragraph (7) of this subdivision may constitute the record of the initial filling of those prescriptions. The daily record may be maintained by a manual system or, alternatively, by an electronic data processing system which meets the following requirements:

(i) the system shall provide adequate safeguards against improper manipulation or alteration of stored records.

(ii) arrangements shall be made which assure completeness and continuity of prescription records if the relationship between a pharmacy and a supplier of data processing services terminates for any reason.

(iii) the system shall provide retrieval of information regarding original dispensing and the refilling of prescriptions.

(iv) a pharmacist, and a pharmacy intern, if applicable, using a computerized system shall sign or initial the original prescription at the time of the first dispensing as provided in paragraph (3) of this subdivision and the initials of the pharmacist shall be entered into the computer record of the dispensing.

(v) for all refills of a prescription, the records introduced into the system shall be sufficient if:

(a) the initials of the pharmacist who dispensed the refill are entered at the time of dispensing; and

(b) a printout is produced of all prescriptions filled and refilled each day and the pharmacist(s) whose initials appear(s) on the printout sign(s) the printout to indicate that it is an accurate record.

(vi) a pharmacy that employs a computerized system shall have an auxiliary procedure which shall be used for documentation of all new and refilled prescriptions dispensed during system downtime. The auxiliary procedure shall provide for the entry into the computer of all data collected during the downtime, and the pharma-

cist shall insure that the maximum number of refills authorized on the original prescription has not been exceeded.

(vii) only pharmacists and pharmacy interns shall enter prescription data into the computerized system, and only pharmacists and pharmacy interns shall access the data.

(9) except as otherwise provided in 16 CFR Part 1700, failure to package a drug in a child-resistant container unless either the prescriber or the patient requests otherwise. Such request shall be documented in the records of the pharmacy. Child- resistant containers shall not be reused;

(10) failure by each pharmacist or pharmacy intern on duty to wear a clearly visible badge prepared in accordance with either of the following specifications:

(i) (a) the badge shall measure at least 1" by 3" and shall be white with black lettering; and

(b) the name of the pharmacist or of the pharmacy intern shall constitute the first line. The title "Pharmacist" or "Pharmacy Intern", whichever is applicable, shall constitute the second line. No other marking or information of any kind shall appear on the badge; and

(c) the name of the pharmacist or of the pharmacy intern shall appear on the badge in the same form as it appears on the current registration or the limited permit. Initials may be used for the middle name and for the first name, if necessary, because of space limitation; or

(ii) a pharmacist or a pharmacy intern practicing in a hospital or other health care facility may wear a badge of such design adopted by the institution for the identification of all health care professionals provided that the badge indicates clearly the wearer's name and the title "Pharmacist" or "Pharmacy Intern";

(11) advertisements of the prices of prescription drugs which do not comply with the following provisions:

(i) the advertised price shall be in effect for a period of time stated in the advertisement;

(ii) when the advertising of prescription prices forms part of a larger advertisement which includes the offering of general merchandise, the advertising pertaining to prescription prices shall be separated physically, such as by a

box, from the advertising pertaining to general merchandise;

(iii) nothing in this subdivision shall be construed to prevent the use in advertising of a statement to the effect that the price for which any prescription will be filled is available on request;

(iv) such advertisement shall comply with the "Prescription Drug Consumer Price Listing" requirements set forth in section 200.200 of Title 21 of the Code of Federal Regulations, as amended;

(12) advertising or soliciting professional practice by means of providing physicians, or others authorized to prescribe, with prescription blanks imprinted with either the name of the pharmacist or the name of the pharmacy;

(13) failing to make prescription fee or price information readily available by providing such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone;

(14) placing in stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; provided, however, that in a health care facility, including but not limited to a general hospital, which has its own pharmacy and in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and labeled with the name of the drug, dosage strength, manufacturer's control number and expiration date, the unused unit dose of medication may be returned to the pharmacy of the facility for redispensing; and provided further that unused medication may be returned to pharmacies by residential health care facilities in accordance with the provisions of 10 NYCRR 731.12 (o).

(15) repacking of drugs in a pharmacy except by a pharmacist or under his or her immediate and personal supervision. Labels on repacked drugs shall bear sufficient information for proper identification and safety. A repacking record shall be maintained including the name, strength, lot number, quantity and name of the manufacturer and/or distributor of the drug repacked, the date of the repacking, the number of packages prepared, the number of dosage units in each

package, the signature of the person performing the repacking operation, the signature of the pharmacist who supervised the repacking and such other identifying marks added by the pharmacy for internal recordkeeping purposes. Drugs repacked for in-house use only shall have an expiration date twelve months or fifty percent of the time remaining to the manufacturer's expiration date, whichever is less, from the date of repacking. For the repacking of drugs by manufacturers and wholesalers, the provisions of Parts 210 and 211 of Title 21 CFR shall apply. Repacking records shall be maintained for five years and shall be made available to the department for review and copying;

(16) holding for sale, offering for sale and selling adulterated and/or misbranded drugs, devices and cosmetics. Any drug, device or cosmetic shall be deemed to be adulterated and/or misbranded if:

(i) it is not manufactured in accordance with the good manufacturing practices specified in Parts 210 and 211 of Title 21 CFR as amended; provided that a drug manufactured by a pharmacy for in-house use may be manufactured in accordance with protocols, including documentation by means of a batch record, which insure the meeting of established standards for purity and potency; and

(ii) at any time it fails to meet standards for purity, potency, labeling, safety and effectiveness established under the Federal Food, Drug and Cosmetic Act, as amended;

(17) holding for sale, offering for sale, or selling:

(i) any drug later than the date, if any, marked upon the label as indicative of the date beyond which the contents cannot be expected beyond reasonable doubt to be safe and effective; provided, however, that when such drug is identified as an outdated drug by segregation from regular stock or by other means, the holding of such drug beyond its expiration date shall not be deemed a violation of this paragraph. When the expiration date is expressed by month and year, the expiration date shall be the last day of the month indicated; or

(ii) any drug, the nature of which requires storage under special conditions of temperature control as indicated

either on the labeling, in the directions for storage of said drug contained in an official compendium, or as directed by common prudence, unless such special condition of temperature control shall have been complied with during the entire period of time in which such drug has been held for sale;

(18)the sale of drugs at auction without filing with the State Board of Pharmacy at least seven days prior to the date of said auction a notice giving the date, time and place of the auction. At such auction, drugs in bulk or in open containers may be sold in one lot only to a registered pharmacy. The drugs shall be removed to the premises of the purchaser promptly and the board notified as to the disposition of such drugs; provided, however, that drugs found by the representative of the board assigned to such auction to be unfit for human use by virtue of age, adulteration and/or misbranding shall be destroyed voluntarily in the presence of the said representative or shall be quarantined by the representative pending action for seizure and destruction;

(19) holding for sale, offering for sale, selling or distributing a new drug or an investigational new drug, which is not recognized as a new drug or an investigational new drug under the provisions of Part 310 or Part 312 of Title 21 CFR;

(20) using colors and dyes in drugs and/or cosmetics which have not been approved for such use under the provisions of the Federal Food, Drug and Cosmetic Act, as amended;

(21) abandoning the premises of a registered establishment. Premises shall be deemed abandoned if the registrant vacates the premises without surrendering the certificate of registration to the State Board of Pharmacy and without making appropriate arrangements for the disposal of prescription-required drugs.

(22) aiding and abetting an unlicensed person to dispense drugs.

(i) Subject to the limitations set forth in subparagraph (ii) of this paragraph, an unlicensed person may assist a pharmacist in the dispensing of drugs by:

(a) receiving written prescriptions;

(b) typing prescription labels;

(c) keying prescription data for entry into a computer-generated file or retrieving prescription data from the

file in accordance with the provisions of subparagraph (ii)(b)(5) of this paragraph;

(d) getting drugs from stock and returning them to stock;

(e) getting prescription files and other manual records from storage and locating prescriptions;

(f) counting dosage units of drugs;

(g) placing dosage units of drugs in appropriate containers;

(h) affixing the prescription label to the container;

(i) preparing manual records of dispensing for the signature or initials of the pharmacist; and

(j) handing or delivering completed prescriptions to the patient or the patient's agent;

(ii) Limitations on assistance by an unlicensed person.

(a) No pharmacist shall obtain the assistance of more than one unlicensed person in the performance of the activities set forth in clauses (b) through (i) of subparagraph (i) of this paragraph.

(b) Unlicensed persons shall not be authorized to:

(1) receive oral prescriptions from prescribers;

(2) interpret and evaluate a prescription for conformance with legal requirements, authenticity, accuracy and interaction of the prescribed drug with other known prescribed and over-the-counter drugs;

(3) determine the product to be dispensed;

(4) measure, weigh, compound or mix ingredients;

(5) prescriptions into or retrieve prescriptions from a computer-generated file, as provided for in subparagraph (vii) of paragraph (8) of this subdivision, except that:

(i) an unlicensed person may key prescription data for the approval of the pharmacist, provided that the pharmacist enters the data into the file along with his or her initials as the dispenser of the prescription; and

(ii) an unlicensed person may retrieve prescription data from the file for review by the pharmacist, provided that when the prescription is to be refilled, the pharmacist shall enter his or her initials as the

dispenser of the refill together with the date on which the prescription was refilled;

(6) sign or initial any record of dispensing required to be maintained by law;

(7) counsel patients; or

(8) perform any other function involving the exercise of professional judgment.

(c) No drug which is dispensed with the assistance of an unlicensed person as provided in subparagraph (i) of this paragraph shall be dispensed without the review and approval of the pharmacist.

(b) Nothing in this Part shall be construed to prevent the ownership of a firm or corporate practice in this State by an unlicensed person or persons or to prevent any contractual arrangement computing the salary of professional employees or the amount due the owner of such firm or corporation or a person leasing space or equipment to such firm or corporation on the basis of a percentage of the receipts from the performance of professional services. This provision shall apply in lieu of paragraph (4) of subdivision (b) of section 29.1 of this Part.

REGULATIONS OF THE COMMISSIONER OF EDUCATION

PART 59

GENERAL PROVISIONS

§ 59.1 Applicability.

(a) As used in this Subchapter, license shall mean a permanent authorization, issued pursuant to Title VIII of the Education Law, to practice a profession or to use a professional title.

(b) The provisions of this Part shall apply to admission to the licensing examination and to the issuance of licenses in each of the professions supervised by the Board of Regents except as may otherwise be provided in this Subchapter with respect to specific professions.

§ 59.2 Education requirements. An applicant for a professional license shall satisfy all education requirements before being admitted to a professional licensing examination. Education requirements for a professional license shall include any preprofessional education or experience required as a prerequisite for admission to a registered program of professional education. The department, in its discretion, may accept in satisfaction of a professional education requirement the completion of an approved or registered program or a program accredited by a professional accreditation organization acceptable to the department. The department, in its discretion, may also accept graduation by a transfer student from such a program provided such student has completed not less than the final year of professional education in such program subsequent to the date of approval, registration or accreditation of the program and approval of the accrediting organization by the department.

§ 59.3 English proficiency requirement. An applicant for licensure whose application is based upon credit granted for the completion of courses of study in a country where English is not the principal language spoken shall demonstrate proficiency in English by passing an examination in English proficiency acceptable to the department or by passing a licensing examination acceptable to the department given in English.

§59.4 Citizenship or immigration status requirements. In those professions where citizenship or immigration status is required for licensure, an applicant shall submit evidence satisfactory to the department of compliance with such requirement.

§59.5 Professional examinations.

(a) The department may develop its own examinations or may select in whole or in part examinations developed or administered by other organizations. Unless specifically authorized by the department, no examination shall be deemed acceptable which has been used in its entirety during the five years previous to the current administration.

(b) Applications for admission to a licensing examination including all required fees shall be completed and filed not less than 60 days prior to the examination. When the department finds that the application is complete and that the requirements for admission to an examination have been met, it will issue to the applicant an admission card which will include the date, time and place of the examination and entitle the applicant to admission thereto. If an application is denied or withdrawn in a timely manner, an applicant may obtain a refund of the first registration fee and a partial refund not exceeding fifty percent of the licensing fee. A request for such a refund shall be made in writing. Reapplication after receipt of a refund may be accepted only upon payment in full of all fees specified.

(c) For the purpose of identification for admission to the examination, the applicant shall present the current admission card with a photograph attached and, at the conclusion of the examination, return the card to the department representative conducting the examination. A candidate shall permit fingerprints to be taken during each part of an examination.

(d) Licensing examinations shall be held at times and places determined by the commissioner and conducted under the following conditions. Any candidate violating such conditions may be dismissed from the examination by the department representative, and the examination paper of such candidate shall be deemed a failure. At the discretion of the department, such candidate may be denied admission to subsequent licensing examinations.

(1) No candidate shall enter any examination more than 45 minutes after the scheduled admission time, nor shall any candidate leave the examination until 60 minutes have elapsed from the scheduled admission time. No candidate shall leave a department administered practical or clinical examination until dismissed by the chief examiner.

(2) Compensatory time may be granted candidates arriving late for an examination, at the discretion of the department.

(3) A candidate shall not obtain unauthorized possession of examination materials.

(4) During the examination, no candidate shall give or receive help, or communicate with any other candidate in any way, except upon the express permission of the department representative.

(5) A candidate shall bring into the examination room only such books and other materials as are indicated on the admission card and permitted by the department.

(6) A candidate shall not remove from the examination room any of the materials provided for an examination, and shall not reproduce or reconstruct any portion of the examination or answer paper, or aid in such reproduction or reconstruction by any means, unless authorized by the department. Such materials include examination booklets, individual examination questions, answer sheets or score sheets, instructions and any reference tables or papers which were provided by the department and which may have been used in the course of the examination.

(e) Papers will be scored and candidates notified of success or failure by the department or its designee. If the candidate has failed, the department will advise when and on what basis the candidate may be reexamined.

(f) The passing score in each component of each part of the licensing examination shall be determined as provided by law and shall be computed without rounding. Unless otherwise provided in the regulations pertaining to a specific profession, a candidate may retain credit for examination parts passed for a period not to exceed five years from the examination date. A candidate who is reexamined in a part already passed shall not retain credit for such part from

earlier examinations. In those professions which use national or regional examinations, this subdivision shall apply whether or not the examination is taken in the State of New York.

(g) In those professions where reviews of examination papers are permitted, candidates will be allowed to review only those parts of the examination which they failed with a score of 65 or higher, except in those professions which permit candidates to pass on average. A request for review of an examination paper or score may be made in writing to the executive secretary of the appropriate state board not later than 30 days after examination grades are released by the department. Such request shall include detailed reasons justifying the review requested. A candidate shall not remove from the reviewing site any of the materials provided for the review of an examination given previously, and shall not reproduce or reconstruct any portion of the examination or the answer paper, or aid in such reproduction or reconstruction by any means, unless authorized by the department. No one other than the candidate will be permitted access to examination materials. Where examinations are offered under contract with testing agencies, reviews shall be consistent with these contracts, where applicable. All reviews shall be conducted at sites selected and supervised by the department or an authorized testing agency.

(h) After July 1, 1984, an applicant who has been admitted to a professional licensing examination conducted by the department and subsequently fails to appear for such an examination twice shall forfeit any remaining fee credits for that examination. The applicant, upon subsequently applying for readmission to that examination, shall pay all required admission fees.

§59.6 License by endorsement. An applicant for endorsement of a license issued by another jurisdiction shall establish that the applicant:

(a) meets all requirements of section 6506 (6) of the Education Law;

(b) has had satisfactory professional experience of at least two years following initial licensure, unless a different period

is provided in the regulations pertaining to a particular profession;

(c) has not attempted unsuccessfully a licensing examination used by the State of New York either prior to or after making application for licensure by endorsement, unless such applicant has later passed a comparable licensing examination.

§59.7 Licenses and initial registrations. When the candidate fulfills all requirements for licensure, the department shall issue a first registration certificate and a license. The first registration shall be for the remainder of the applicable registration period, except that those persons initially licensed during the last four months of a registration period shall be registered for the succeeding registration period without an additional fee.

§59.8 Registration for professional practice.

(a) Each licensee shall be responsible for registering with the department. Failure to register shall subject the practitioner to the late fee set forth in section 6502 (3) of the Education Law. Any practitioner who willfully refuses to register shall be subject to the penalties set forth in section 6511 of such law.

(b) A licensee not practicing or using a restricted title in New York State or an individual practicing only in a setting which is exempt from licensure in accordance with law may allow registration to lapse without being subject to the late fee set forth in section 6502 of the Education Law, by notifying the department of their cessation of practice or exemption in the State. At such time as the licensee may choose to resume practice or enter practice in a nonexempt setting in New York State, a registration certificate may be issued upon the filing of a proper application and the payment of the required registration fee.

(c) Registration certificates shall be conspicuously displayed by each licensee in each office in which the profession is practiced. In instances where licensees regularly practice at more than one professional office, registration certificates shall be obtained for each office bearing the licensee's name and the exact address of each such office upon making proper

application to the department and submitting a fee. Where practice is carried on in other than individual offices, each licensee shall have a current registration certificate available for inspection at all times.

(d) Beginning dates for two-year (biennial) registration periods for each profession shall be as follows:

Professions	Beginning Dates
Professional Engineering, Land Surveying, Massage	11/1/80
Acupuncture, Medicine, Pharmacy, Physical Therapy, Physical Therapist Assistant	1/1/81
Registered Professional Nursing	9/1/81
Chiropractic, Veterinary Medicine, Animal Health Technology, Physician's Assistant, Specialist's Assistant	1/1/82
Social Work	3/1/82
Occupational Therapy, Speech Pathology, Audiology	4/1/82
Dentistry, Dental Hygiene	5/1/82
Optomemtry, Ophthalmic Dispensing, Certified Shorthand Reporting	7/1/82
Licensed Practical Nursing, Architecture, Landscape Architecture, Certified Public Accountant, Public Accountancy	9/1/82
Psychology	5/1/83
Podiatry	9/1/83
Occupational Therapy Assistant	11/1/83

(e) Beginning dates for new three-year (triennial) registration periods shall be as follows:

Professions	Beginning Dates
Professional Engineering, Land Surveying, Massage	11/1/82
Acupuncture, Medicine, Pharmacy, Physical Therapy, Physical Therapist Assistant	1/1/83

Registered Professional Nursing	9/1/83
Chiropractic, Veterinary Medicine, Animal Health Technology, Physician's Assistant, Specialist's Assistant	1/1/84
Social Work	3/1/84
Occupational Therapy, Speech Pathology, Audiology	4/1/84
Dentistry, Dental Hygiene	5/1/84
Optometry, Ophthalmic Dispensing, Certified Shorthand Reporting	7/1/84
Licensed Practical Nursing, Architecture, Landscape Architecture, Certified Public Accountant, Public Accountancy	9/1/84
Psychology	5/1/85
Podiatry	9/1/85
Occupational Therapy Assistant	11/1/85

(f) Each professional practitioner shall notify the department of any change of name or address in writing not later than 30 days after such change.

§ 59.9 Special service fees. The department will charge the following fees for special services not otherwise provided by Education Law:

(a) for the issuance of a trainee permit in ophthalmic dispensing, $15;

(b) for certification of completion of pharmacy internship, $10;

(c) for admission to the history section of the technical examination in landscape architecture, $50 and for each subsequent reexamination, $50, the remainder of the fee set forth in Section 7324 of the Education Law to be paid prior to admission to the remainder of the examination;

(d) for certification of licensure or examination grades to another jurisdiction, $20;

(e) for certification in acupuncture of a licensed physician or dentist, $50;

(f) for the issuance of an additional registration certificate, $5;

(g) for the issuance of a letter of eligibility to undertake clinical clerkships, $30;

(h) for the issuance of a Medical Sciences Knowledge Profile (MSKP) or satisfactory equivalent examination certificate to undertake clinical clerkships, $20.

§ 59.10 Professional service corporations.

(a) Applications to the State Education Department for the issuance of a certificate pursuant to Business Corporation Law section 1503 (b) (ii) shall be made by submitting to the department a fully executed certificate of incorporation which complies with the provisions of such section and of section 1512 of such law, and which sets forth or has annexed to it an affidavit of one of the original officers, directors or shareholders of the corporation setting forth the name of each individual who is to be one of the original shareholders, directors or officers of the corporation.

(b) If the name of a proposed professional service corporation contains the name of a deceased person, the certificate of incorporation, when submitted to the department for the issuance of a certificate pursuant to Business Corporation Law section 1503 (b) (ii) shall be accompanied by an affidavit of one of the subscribers to the certificate of incorporation establishing compliance with the provisions of Business Corporation Law section 1512 (a) (2).

(c) A certificate pursuant to Business Corporation Law section 1503 (b) (ii) may be issued when:

(1) the proposed name of the corporation appropriately describes the profession practiced and the services to be provided;

(2) if the proposed name of the corporation includes a reference to a specialized area of professional practice, satisfactory evidence is submitted of compliance with any provision of Part 29 of the Rules of the Board of Regents restricting or regulating the use of specialty titles or announcements of limitations of practice in the particular profession.

PART 63
PHARMACY

63.1 Professional study of pharmacy.

(a) To meet the professional education requirement for admission to the licensing examination, the applicant shall present evidence of either:

(1) the completion of a program of pharmacy education of not less than three academic years of professional study, or the equivalent thereof, registered by the department or accredited by an accrediting organization acceptable to the department; or

(2) the completion of a nonregistered or nonaccredited program in pharmacy, including a foreign pharmacy program, of not less than three academic years of professional study, or the equivalent thereof, satisfactory to the department. The program of study in a foreign school of pharmacy shall culminate in the awarding of a degree, diploma or certificate in pharmacy recognized by the appropriate civil authorities of the country in which the school is located as meeting the educational requirement for entry into practice in that country.

(b) A program of pharmacy education shall be considered completed upon certification of completion by the school in which such program was taken and proof that the applicant has been awarded the appropriate pharmacy degree, diploma or certificate.

§ **63.2 Experience.** For admission to the licensing examination:

(a) Graduates of registered or accredited programs leading to the bachelor's degree in pharmacy shall have completed at least six months of full-time experience, or the equivalent thereof, as a pharmacy intern in an internship program which meets the following requirements:

(1) Program requirement. The internship program shall be devoted to the preparing, compounding, preserving and dispensing of drugs, medicines and therapeutic devices and to the performance of the functions related thereto, such as

the counseling of patients and the monitoring of drug regimens, under the supervision of a registered pharmacist.

(2) Time requirement. The six months shall be completed in accordance with the following:

(i) Any portion or all of the internship may be completed during periods subsequent to the successful completion of the first year of a professional education program in pharmacy and not concurrent with full-time enrollment in such a program;

(ii) Any portion or all of the internship may be completed subsequent to the award of a degree in pharmacy which meets the requirement of section 63.1 of this Part;

(iii) Part-time supervised practice completed pursuant to the provisions of subparagraphs (i) and (ii) of this paragraph may be granted proportionate credit. For the calculation of equivalencies, "full time" shall be defined as forty hours per week.

(3) Preceptor pharmacist requirement. The registered pharmacist who supervises an intern shall be designated the preceptor pharmacist. Each preceptor pharmacist shall have practiced for at least one year immediately preceding assuming a preceptorship. The preceptor pharmacist shall have under his or her supervision not more than one full-time intern nor more than two part-time interns.

(4) Additional requirement. In each pharmacy which will serve for the training of interns, one intern may be engaged for each 5000 prescriptions and/or drug orders dispensed annually and for a major fraction thereof over a multiple of 5000.

(b) Graduates of nonregistered and nonaccredited programs, including foreign programs in pharmacy, shall be authorized to begin an internship only after passing Part I of the pharmacist licensing examination. Thereafter, the applicant shall complete not less than twelve months of full-time experience, or the equivalent thereof, in an internship program which meets the requirements of paragraphs (1), (3) and (4) of subdivision (a) of this section. Upon completion of the internship program, the applicant may be admitted to the practical portions (Parts II and III) of the examination.

(c) Graduates of registered or accredited programs leading to the Doctor of Pharmacy degree shall be considered to have completed the internship requirement.

§ 63.3 Licensing examinations.

(a) Content. The examination shall consist of three parts:

Part I. Applied chemistry, mathematics, pharmacology and pharmaceutics and clinical pharmacy.

Part II. Professional law, ethics and professional conduct, prescription and nonprescription required drugs and prescription problems.

Part III. Prescription compounding and pharmacy practice.

(b) The department may accept satisfactory scores on an examination of the National Association of Boards of Pharmacy as meeting the requirements of Part I of the licensing examination.

(c) Passing score. The passing score in each part of the examination shall be 75.0, as determined by the State Board of Pharmacy.

(d) Special condition. A graduate of a registered or accredited program of education who has not completed the required practical experience may be admitted to Part I of the examination only.

§63.4 Limited permits.

(a) A limited permit, identifying the holder as a pharmacy intern and authorizing the practice of pharmacy under the immediate and personal supervision of a registered pharmacist, may be issued in accordance with the provisions of section 6806 of the Education Law to:

(1) an applicant enrolled in a program of pharmacy education registered or approved by the department who has completed at least the third year of a five- or six-year program.

(2) a graduate of a nonregistered or nonaccredited pharmacy program, including a foreign pharmacy program, for the purpose of completing the experience requirement set forth in subdivision (b) of section 63.2 of this Part.

(b) A limited permit shall be displayed conspicuously in the pharmacy where the pharmacy intern is engaged for supervised practice.

(c) A pharmacy intern may perform, under the supervision of a preceptor pharmacist, all of the functions delegated to pharmacists by law, rule or regulation.

§ 63.5 License as a pharmacist by endorsement. For endorsement of a pharmacist license issued by another jurisdiction, the applicant shall:

(a) present evidence of having met all requirements of section 59.6 of this subchapter, except that the applicant shall have had, during the five years preceding the filing of the application, at least one year of satisfactory experience following licensure; and

(b) pass an examination on the laws, rules and regulations pertaining to the practice of pharmacy in New York administered by the State Board of Pharmacy.

§ 63.6 Registration and operation of establishments.

(a) General provisions.

(1) A certificate of registration issued for the operation of a pharmacy, manufacturer, wholesaler or registered store shall be valid only for that address stated on the certificate. Endorsement of the certificate to another address may be made by the State Board of Pharmacy upon application to the board, the payment of the fee set forth in Education Law section 6808 and a finding by the board that the new location meets the requirements of the applicable subdivisions of this section. An application for endorsement to another address shall be made not less than thirty days prior to the expected date of relocation.

(2) In the case of a corporation, the State Board of Pharmacy shall be notified within thirty days of any change in the officers of the corporation or in stockholders holding ten percent or more of the stock in the corporation.

(3) No certificate of registration shall be issued or continued for the conduct of a pharmacy, manufacturer, wholesaler or registered store unless the premises occupied by such registered establishment shall be equipped with proper sanitary appliances and kept in a clean and orderly manner.

(4) The State Board of Pharmacy shall be notified within a period of forty- eight hours whenever any establishment

registered by the board is damaged by fire, flood or other disaster.

(5) The State Board of Pharmacy shall be notified within seven days of any change in the identity of the supervisor of a registered establishment.

(6) Signs upon establishments. Except as otherwise provided for pharmacies in general merchandising establishments in paragraph (5) of subdivision (b) of this section, a sign bearing the full name of the registrant shall be displayed prominently on the exterior of the premises in which a registered establishment is located, or in the directory and on the immediate entrance to the registered establishment, if it is located in a multitenanted structure.

(b) Pharmacies.

(1) To secure and retain registration, a pharmacy shall be equipped with at least the following utensils:

(i) balance sensitive to 6 mg.;

(ii) metric and apothecary weights;

(iii) graduates capable of measuring volumes from 5 minims to at least 1 pint and from 1 ml to 500 ml; and

(iv) a mortar and pestle.

(2) The registered area shall measure not less than 300 square feet and shall include a manufacturing, compounding and dispensing area of not less than 100 square feet. The pharmacy shall be equipped with storage facilities providing for the safe storage of drugs; with heating and ventilation adequate to safeguard the purity and potency of drugs; with adequate lighting; and with hot and cold running water in the compounding and dispensing area; provided, however, that a pharmacy which was registered initially prior to the effective date of this paragraph on the basis of meeting requirements less than those specified in this paragraph shall not be required to meet the requirements of this paragraph for the continuance of registration to the same registrant.

(3) The registered area shall include a refrigerator, sufficient in capacity to serve the needs of the pharmacy, that is equipped with a thermometer and providing at all times a storage temperature of 0 degrees to 15 degrees Centigrade (32 degrees to 59 degrees Fahrenheit). The use of such refrigerator shall be limited to the storage of drugs.

(4) The pharmacy shall possess the latest editions of the United States Pharmacopeia/National Formulary and the United States Pharmacopeia Dispensing Information, together with all supplements thereto, copies of laws, rules and regulations governing the practice of pharmacy in New York and other reference books as may be necessary to carry on practice.

(5) A pharmacy operated as a department of a general merchandising establishment shall be enclosed permanently by a partition at least nine feet six inches in height except where the ceiling is less than nine feet six inches in height in which case the partition shall be from floor to ceiling. Identification of such department by use of words "drugs", "medicines", "drug store" or "pharmacy" or similar terms shall be restricted to the area registered by the department except that nothing in this restriction shall prevent the placement on the exterior of such establishment of signs indicating the existence of a pharmacy therein. Such exterior signs may consist of the name of the registrant and/or the word "pharmacy"; provided, however, that when the word "pharmacy" is used, it may not be used in juxtaposition to a nonregistered name. When the pharmacy is not open during all the hours maintained by the general merchandising establishment, an exterior sign shall indicate clearly when the pharmacy is open and when it is closed.

(6) A pharmacy in which radioactive drugs are dispensed shall meet all requirements established by 10 NYCRR Part 16 for medical and academic facilities or by 12 NYCRR Part 38 for commercial facilities as evidenced by receipt by the pharmacy of an appropriate license issued by the New York State Department of Health or the New York State Department of Labor, and the additional requirements which follow.

(i) There shall be present at all hours when the pharmacy is open at least one pharmacist who:

(a) meets the minimal standards of training and experience required by 10 NYCRR Part 16 or by 12 NYCRR Part 38 for the use of radioactive materials; and

(b) has submitted to the State Board of Pharmacy evidence of either of the following:

(1) certification as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties of the American Pharmaceutical Association; or

(2) completion of a minimum of 200 contact hours of didactic instruction in nuclear pharmacy in an accredited school or college of pharmacy and a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a Board of Pharmaceutical Specialties certified nuclear pharmacist in a pharmacy providing nuclear pharmacy services, in a certified nuclear pharmacy residency program or in a nuclear pharmacy training program in an accredited school or college of pharmacy or the equivalent thereof as determined by the department.

(ii) In addition to the items and articles of equipment required by this subdivision, the pharmacy shall be equipped with at least the following:

(a) laminar flow hood
(b) dose calibrator
(c) exhaust hood and filter system
(d) chromatography apparatus
(e) apparatus or materials for the determination of pH
(f) single channel and/or multichannel scintillation detection system
(g) microscope

(iii) A pharmacy which dispenses both radioactive drugs and nonradioactive drugs shall maintain a separate area for the storage and dispensing of radioactive drugs which area shall be secured from unauthorized personnel.

(c) Manufacturers and wholesalers.

(1) Except as provided in paragraph (2) of this subdivision, no manufacturer or wholesaler shall be registered pursuant to the provisions of subdivision 4 of section 6808 of the Education Law unless a registered pharmacist is present at all times when the establishment is open for business, provided, however, that such establishment may be under the supervision of a chemist who holds a bachelor's degree with a major in chemistry and who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs satisfactory to the State Board of Pharmacy.

(2) Wholesalers who do not repack may designate as the supervisor a person who presents evidence of the completion of a minimum of two years of education beyond high school and who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs satisfactory to the State Board of Pharmacy.

(3) The supervisor of an establishment designated pursuant to paragraphs (1) and (2) of this subdivision shall not be at the same time the supervisor of any other establishment registered by the board.

(4) The size and facilities of a registered establishment shall be appropriate for the activities to be conducted therein. The registered area shall not be shared with or be devoted in part to any other business.

(5) Manufacturers or wholesalers shall sell drugs and/or devices only to those purchasers authorized by law. Records of the receipt and disposition of all drugs and/or devices shall be maintained for a period of five years and shall be available to the department for review and copying.

(6) Certification of manufacturers and wholesalers for export purposes. Any registered manufacturer or wholesaler may be issued a certificate by the Executive Secretary of the State Board of Pharmacy, authenticating said registration and identifying the specified drugs and/or devices as articles regularly offered for sale in New York. The fee for each certificate shall be five dollars.

(d) Registered stores.

(1) All certificates granted registered storekeepers shall contain a list of the articles which may be sold under this form of registration. Such articles shall be sold in original packages only and shall be labeled in accordance with the provisions of section 6815 (2) of the Education Law and of section 29.7 (a) (16) of the Rules of the Board of Regents.

(2) The sale of the articles listed on the certificate shall be made by the storekeeper whose name appears on the certificate.

APPENDIX

Examinations

Examinations for licenses to practice pharmacy are held in Albany, Buffalo and New York City in January and June of each year. Complete application materials should be submitted at least 60 days prior to the date of the examination.

Nature of the Examination

The examination is divided into three parts.

PART I consists of the National Association of Board of Pharmacy NABPLEX examinations in mathematics, pharmacology, chemistry, pharmacy and the practice of pharmacy. The mathematics and pharmacology examinations are administered in the morning of the first day. The chemistry and pharmacy examinations are administered in the afternoon of the first day. The practice of pharmacy examination is administered in the morning of the second day. The competency statements upon which the NABPLEX examinations are based and sample questions may be found in the NABPLEX Candidate's Guide. The Guide may be obtained from the National Association of Boards of Pharmacy, One East Wacker Drive, Chicago, Illinois 60601 at a cost of $7.50.

PART II is a short-answer examination in professional law, ethics and professional conduct, prescription and nonprescription required drugs and prescription problems. It is administered in the afternoon of the second day.

PART III consists of a laboratory examination in compounding and dispensing, written examinations on patient profiles, errors and omissions, sickroom supplies and home health care and an audio exercise. The examination is administered in two sessions, morning and afternoon on the same day.

Each Part of the examination must be passed independently. The passing score on each Part is 75.0. A candidate may retain credit for examination Parts passed; only failed Parts need be

repeated. However, credit for a Part passed may not be retained for a period to exceed five years from the examination date.

Applicants may be admitted to the full examination after they have completed all of the requirements for admission. Graduates of registered or accredited programs who meet all of the requirements except the internship requirement will be admitted to Part I. Upon completing the internship requirement, they will be admitted to Parts II and III.

Graduates of nonregistered and nonaccredited programs in pharmacy, including foreign programs, are admitted to Part I upon approval of their academic qualifications. After passing Part I, they are authorized to begin an internship. Upon the completion of a one- year internship acceptable to the Board, they will be admitted to Parts II and III of the examination.

Selected List of Other Laws
Governing the Distribution, Sale and Dispensing of Drugs

NEW YORK STATE

New York State Controlled Substances Act
Article 33 of the Public Health Law

Chapter II of the Administrative Rules and Regulations
Subchapter J, Part 80
Rules and Regulations on Controlled Substances

Information concerning and copies of the above may be obtained from:

New York State Health Department
Bureau of Narcotic Control
Fourth Floor -- Tower Building
Empire State Plaza
Albany, New York 12237

Safe, Effective and Therapeutically Equivalent Prescription Drugs (Required by Section 206, subdivision (1), paragraph (o) of the Public Health Law).

Copies may be obtained at a cost of $2.75 from:

Health Education Services
P.O. Box 7126
Albany, New York 12224

FEDERAL

Comprehensive Drug Abuse Prevention and Control Act of 1970
Public Law 91-513

Information concerning and copies of the above may be obtained from:

U.S. Department of Justice
Drug Enforcement Agency
555 West 57th Street
New York, New York 10019

Federal Food, Drug and Cosmetic Act
as amended January 1971

Poison Prevention Packaging Act of 1970
Public Law 91-601

Code of Federal Regulations
Title 21
Food and Drugs

Copies of the above may be obtained from:
Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

NEW YORK STATE
COLLEGES OF PHARMACY

Long Island University
Arnold and Marie Schwartz
College of Pharmacy and Health Sciences
75 DeKalb Avenue
Brooklyn, New York 11201
Dr. John J. Sciarra, Dean
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St. John's University
College of Pharmacy and Allied Health Professions
Grand Central and Utopia Parkways
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State University of New York at Buffalo
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Cooke Hall
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